CC:

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; Mclain, Jennifer

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[Guilaran.Yu-Ting@epa.gov]; Risley, David [Risley.David@epa.gov]

Attachments: OGWDW Biweekly_091319.docx; Perchlorate Comment Summary V4.pdf; Copy of LCR Revisions Proposal Schedule

9-12-19.pdf

Location: 3233 WJCE

Start: 9/13/2019 3:00:00 PM **End**: 9/13/2019 3:45:00 PM

Show Time As: Busy

Recurrence: (none)

OGWDW Bi-Weekly with OW September 13, 2019

Agenda

- Perchlorate Comments
- LCR Revisions
- Lead Free Final Rule
- WIIN Grants
- Denver Variance
- NRWA WaterPro Conference

NPDWR for Perchlorate Proposal: Summary of Public Comments

EPA received a total of 1,495 comments in response to its perchlorate rulemaking proposal.

<u>Mass Mailing Campaign:</u> 1,386 comments were received under a mass mailing campaign. These commenters oppose the proposed Maximum Contaminant Level of 56 μ g/L stating that as proposed the MCL is too high to adequately protect the health of communities throughout the country.

<u>Individuals</u>: Eighty-one comment letters with varied levels of complexity were submitted by individuals. These letters cover a wide array of technical and policy issues regarding the perchlorate proposal (88 pages).

- 6 support the 56 μg/L proposal.
- 1 supports the 90 μg/L alternative.
- 6 support the 18 μ g/L alternative.
- 23 support regulation at a level lower than 18 μ g/L.
- 1 supports the withdrawal of the regulatory determination.
- 44 are in general opposition and/or out of scope.

<u>Extensive and Substantive Comment Letters from Organizations:</u> Twenty-eight comment letters containing extensive and substantive technical and policy issues were submitted (657 pages). The overall recommendation of these comment letters on the regulatory proposal breakdown as follows.

- One organization did not take a position regarding regulation of perchlorate:
 - Association of State Drinking Water Administrators
- None support the proposed 56 μg/L proposal.
- None support the 90 µg/L alternative.
- Two support the 18 µg/L alternative:
 - o Oregon
 - Virginia
- Fourteen support regulation at a level lower than 18 μg/L:
 - Association of California Water Agencies
 - o Metropolitan Water District of Southern California
 - California
 - Massachusetts
 - New Jersey
 - New York
 - o The Salt River Pima-Maricopa Indian Nation
 - o The Tohono O'odham Nation
 - Alaska Community Action on Toxics
 - o Environmental Defense Fund
 - Environmental Protection Network
 - Environmental Working Group
 - Natural Resources Defense Council
 - American Academy of Pediatrics

NPDWR for Perchlorate Proposal: Summary of Public Comments

• Eleven support withdrawal of the determination to regulate perchlorate:

U.S. Conference of Mayors & the National League of Cities (joint letter)

South Dakota

California Farm Bureau Federation

American Water

El Paso Water

American Chemistry Council

American Water Works Association

Association of Metropolitan Water Agencies

National Rural Water Association

Perchlorate Study Group

The Chlorine Institute

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Klein, Melissa [Klein.Melissa@epa.gov]

Attachments: OGWDW Bi-Weekly_103119.docx

Location: 3233 WJCE

Start: 10/31/2019 2:30:00 PM **End**: 10/31/2019 3:00:00 PM

Show Time As: Busy

Recurrence: (none)

OGWDW Bi-Weekly with OW

October 31, 2019

Agenda

- PFAS
- Regulatory Determinations for CCL 4 Contaminants: FAR and OMB Review
- LCR Proposed Revisions Big 10 Meeting and NDWAC Consultation
- Perchlorate Option Selection and NDWAC Consultation
- Lead Free Final Rule
- ESF-3
- CA Wildfires
- Industrial Control System Interagency Working Group and Federal Senior Leadership Council Meeting
- UCMR5

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Attachments: OGWDW Bi-Weekly_111419.docx

Location: 3233 WJCE

Start: 11/14/2019 4:00:00 PM **End**: 11/14/2019 4:30:00 PM

Show Time As: Busy

Recurrence: (none)

OGWDW Bi-Weekly with OW November 14, 2019

Agenda

- Regulatory Determinations CCL 4 Contaminants
- Reducing Lead in Drinking Water Grant Request for Applications WIIN Act Section 2105
- Emergency Support Federal Leadership Group
- Perchlorate Option Selection Briefings

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

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Klein, Melissa [Klein.Melissa@epa.gov]

Attachments: OGWDW Bi-Weekly_121019.docx

Location: 3233 WJCE

Start: 12/10/2019 2:30:00 PM **End**: 12/10/2019 3:00:00 PM

Show Time As: Tentative

Recurrence: (none)

To:

Fuld, John [Fuld.John@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Thompkins, Anita [Thompkins.Anita@epa.gov]; Travers, David [Travers.David@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Tovar, Katlyn [tovar.katlyn@epa.gov]; Dennis, Allison [Dennis.Allison@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; McLain, Jennifer L. [Mclain.Jennifer@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; McLain, Jennifer L. [Mclain.Jennifer@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Dennis, Allison [Dennis.Allison@epa.gov]; Tovar, Katlyn [tovar.katlyn@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Travers, David [Travers.David@epa.gov]; Thompkins, Anita [Thompkins.Anita@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Fuld, John [Fuld.John@epa.gov]; Campbell, Ann [Campbell.Ann@epa.gov] Macara Lousberg [Lousberg.Macara@epa.gov]; Klein, Melissa [Klein.Melissa@epa.gov]; Gordon, Brittney [Gordon.Brittney@epa.gov]; Risley, David [Risley.David@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov];

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Subject: Attachments: Brownbag -Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP)

OGWDW Bi-Weekly_03112020_v1.docx

Location: 3233 WJCE

Start: 3/11/2020 4:15:00 PM End: 3/11/2020 5:00:00 PM

Show Time As: Busy

Recurrence: (none)

every 2 week(s) on Wednesday from 4:00 PM to 4:45 PM

OGWDW Bi-Weekly with OW

March 11, 2020

Agenda

- Water Security
 - Report out: March 4th Executive Engagement Forum Cross Sector Control Systems Interagency Working Group
 - o DHS COVID-19 Guidance
 - o ESF-3
- COVID-19
- Perchlorate
- LCRR
- Lead Free
- PFAS
- EPA's Office of Children's Health Protection Upcoming Activities
- Heads Up
 - Quarterly Meeting w/Tracy Mehan and others
 - o Wyoming Underground Injection Control Program; Class VI Primacy
 - Water System Partnership State Handbook

OGWDW Actions in OW-IO for Input

- Perchlorate
 - o Steps Water Systems Can Take to Address Perchlorate in Drinking Water
 - Reductions of Perchlorate in Drinking Water
 - Paper Based Briefing
- America's Workforce Initiative FRN
- Water Operator Hiring Guide
- Allotments of FY2020 Appropriations for the Voluntary Lead Testing in School and Child Care Program
 Drinking Water Grants, Authorized under Section 2107 of the Water Infrastructure Improvements for
 the Nation Act
- OGWDW Workplan Follow-up
- SDWIS Modernization Board Announcement for sharing with ECOS & ASDWA communities
- Challenges in Expediting Promulgation of Final Lead and Copper Rule Revisions

<u>Upcoming External Engagements/Document Release Info/Events</u>

3/10	Report. Issue to USAID the OITA cleared, "Trip Report from Preliminary Assessment of Las Pavas Water Treatment Plant and Distribution System."
3/10	Staff presentation. PFAS and the Safe Drinking Water Act to the American Water Resources Association (AWRA) National Capital Regional Section (NCRS) at Howard University
3/12	Webinar Recording. Implementation of Capacity Development Program – Related Safe Drinking Water Act Amendments in the America's Water Infrastructure Act
3/12	Webinar Recording. WIIN Grant: Reduction in Lead Exposure Via Drinking Water Request for Applications
3/18	Conference call. ASDWA regarding LCRR Costs model

To:

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Subject: Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP)

Attachments: OGWDW Bi-Weekly_02112020_V1.docx

Start: 2/12/2020 3:00:00 PM **End**: 2/12/2020 3:30:00 PM

Show Time As: Busy

Recurrence: (none)

every 2 week(s) on Wednesday from 4:00 PM to 4:45 PM

OGWDW Bi-Weekly with OW

February 12, 2020

Agenda

- Lead Free
- Reg Det
- PFAS
- Workforce
- Perchlorate
- Technical Assistance Grant
- ESF-3 Update
- Groundwater Protection Council 2020 UIC Conference

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Attachments: OGWDW Bi-Weekly_01302020_v1.docx

Start: 1/30/2020 3:15:00 PM End: 1/30/2020 4:00:00 PM

Show Time As: Tentative

Recurrence: (none)

every 2 week(s) on Wednesday from 4:00 PM to 4:45 PM

OGWDW Bi-Weekly with OW January 30, 2020

Agenda

•	Lead	ΙFι	ree

- Reg Det
- PFAS
- Workforce
- Perchlorate
- USDA MOA
- PG&E Speaker for March 3 and March 4 EPA Water Sector PSPS Exercises
- OITA Request for Technical Assistance for El Salvador
- Heads up
 - o PWSS Implementation Memo
 - o Administrator Wheeler's Visit to EPA Cincinnati

To: Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov];

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Subject: Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP)

Attachments: OGWDW Bi-Weekly_022620 20:00cx

Start: 2/26/2020 3:00:00 PM **End**: 2/26/2020 3:45:00 PM

Show Time As: Busy

Recurrence: (none)

every 2 week(s) on Wednesday from 4:00 PM to 4:45 PM

OGWDW Bi-Weekly with OW

February 26, 2020

Agenda

- Perchlorate
- Lead Free
- PFAS
- Update on Grants
 - Public Water System Supervision Grants, Funding for PFAS and other Contaminants of Emerging Concern
 - Small System Training and Technical Assistance Grant
 - ASDWA
- Cyber
 - March 4th Executive Engagement Forum Cross Sector Control Systems Interagency Working Group
 - Response Role
 - Cyber Meeting 2/28
- Heads Up
 - o Memo to EPA Regions FY20 WIIN Grant allotments for Lead in Schools
 - Public Webinar WIIN Lead RFA, Tuesday March 3rd
 - Public Announcement SDWIS Modernization Board (EPA, ECOS, and ASDWA)
 - Approval Memo AlS Waiver for Boone County Public Service District, West Virginia
 - FAQs for EPA Regions and States One Year Inter-SRF Transfer Authority to Address Lead in Drinking Water

To:

Fuld, John [Fuld.John@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Thompkins, Anita [Thompkins.Anita@epa.gov]; Travers, David [Travers.David@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Tovar, Katlyn [tovar.katlyn@epa.gov]; Dennis, Allison [Dennis.Allison@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Best-Wong, Benita [Best-Wong, Benita@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; McLain, Jennifer L. [Mclain.Jennifer@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Forsgren,

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Subject: Bi-Weekly w/OGWDW

Attachments: OGWDW Biweekly Agenda 04302020.docx Location: Call in Ex. 6 Personal Privacy (PP)

Start: 4/30/2020 7:30:00 PM **End**: 4/30/2020 8:00:00 PM

Show Time As: Busy

Recurrence: (none)

every 2 week(s) on Wednesday from 4:00 PM to 4:45 PM

Attendee list adjusted to be OGWDW OD, DOD, and Special Assistant only.

OGWDW Bi-Weekly with OW April 30, 2020

Agenda

- COVID-19
 - o FEMA Distribution of Reusable Cloth Masks to Water Sector
 - Flushing Guidance Protocols for Maintaining or Restoring Water Quality in Buildings with Low or No Use
 - Chemical Supply Chain CO2 Map; Defense Production Act resources
 - Webinar for EPA Regions and Primacy Agencies on Existing Drinking Water Regulatory Flexibilities. Drafting FAQs for website.
 - o Meetings with Stakeholders
- Section 1459A Grants
- Perchlorate Final Agency Review & OGC/DOJ Next Steps
- Cybersecurity "Tiger Team"
- Lead and Coper Rule Revisions
- Lead Free OMB Pass Back

OGWDW Actions in OW-IO for Input

- Flushing Guidance for Resuming/Initiating Service at Larger Buildings
- CO2 Map
- Section 1459A Grants Briefing Follow-up Next steps
 - We briefed Dave, Charlotte, and Lee a few weeks ago and need to know what else do they need to make decisions and for us to move forward

Heads Up

• Federal Resources for Tribal Communities - Under Development.

External engagements/document release info:

- 5/1 Webinar Posting: WIIN Assistance for Small and Disadvantaged Communities Grant.
- 5/1 Webinar Posting: COVID-19 Planning and Response: Overview of EPA's Pandemic Incident Action Checklist for Tribal Water Utilities.
- 5/1 Meeting. AWWA Water Utility Council.

To:

Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Dennis, Allison [Dennis.Allison@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Travers, David [Travers.David@epa.gov]; Thompkins, Anita [Thompkins.Anita@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Fuld, John [Fuld.John@epa.gov]; Fuld, John [Fuld.John@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Thompkins, Anita [Thompkins.Anita@epa.gov]; Travers, David [Travers.David@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Tovar, Katlyn [tovar.katlyn@epa.gov]; Dennis, Allison [Dennis.Allison@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; McLain, Jennifer L. [Mclain.Jennifer@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Owscheduling [Owscheduling@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; McLain, Jennifer L. [Mclain.Jennifer@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Campbell, Ann [Campbell.Ann@epa.gov]

CC:

Lousberg, Macara [Lousberg.Macara@epa.gov]; Risley, David [Risley.David@epa.gov]; Gordon, Brittney [Gordon.Brittney@epa.gov]; Klein, Melissa [Klein.Melissa@epa.gov]; Klein, Melissa [Klein.Melissa@epa.gov]; Gordon, Brittney [Gordon.Brittney@epa.gov]; Risley, David [Risley.David@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Lousberg, Macara [Lousberg.Macara@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Tovar, Katlyn [tovar.katlyn@epa.gov]; Braschayko, Kelley [braschayko.kelley@epa.gov]

Subject: Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP)

Attachments: OGWDW Biweekly_Agenda_04142020_v1.docx

Location: 2029910477, 1300632#

Start: 4/14/2020 8:00:00 PM **End**: 4/14/2020 8:30:00 PM

Show Time As: Busy

Recurrence: (none)

every 2 week(s) on Wednesday from 4:00 PM to 4:45 PM

Attendee list adjusted to be OGWDW OD, DOD, and Special Assistant only.

OGWDW Bi-Weekly with OW April 14, 2020

Agenda

- Lead and Coper Rule Revisions
- Lead Free OMB Pass Back
- COVID-19
 - Chemical Supply Chain Issues
 - FEMA Public Assistance Funding
- Perchlorate FRN Final Agency Review
- Cybersecurity "Tiger Team"
- Committee on Foreign Investment in the United States (CFIUS)

OGWDW Actions in OW-IO for Input

- COVID-19 Tribal Water Utility Template
- COVID-19 Implications for Drinking Water and Clean Water Programs
- Prioritization of Water Sector Employee Testing and PPE Distribution during COVID-19 Letter from Administrator Wheeler to Secretary Azar
- OGWDW Workplan and disinvestment Follow-up.
 - Ex. 5 Deliberative Process (DP)
- America's Water Sector Workforce Initiative: A Call to Action
 - Includes Email to Federal Partners Seeking Concurrence to Publish the FRN
- Section 1459A Grants Briefing Follow-up Next steps
 - We briefed Dave, Charlotte and Lee- a few weeks ago and need to know what else do they need to make decisions and for us to move forward

Heads Up

- UIC Program at-a-Glance Fact Sheet.
- Flushing Guidance for Resuming/Initiating Service at Larger Buildings Under Development.
- Federal Resources for Tribal Communities.

External engagements/document release info:

- 4/9 Meeting. Sustainable Systems Staff monthly meeting with ASDWA.
- 4/9 GWPC Selection for the FY20 UIC and Source Water Competitive Grant sent to OGD.
- 4/14 Meeting. Quarterly with NGOs.
- 4/14 Webinar. EPA's Pandemic Incident Action Checklist with Tribal Water and Wastewater Utilities.
- 4/15 Announcement. SDWIS Modernization Board formation (communication approved by OW on 3/18) shared today by ASDWA and ECOS to their communities.

- 4/16 Meeting. Virtual SRF State-EPA Workgroup.
- 4/20 Memorandum.
 - AIS Waiver Request Decision Memorandum:
 - o Central Utah Water Conservancy District, UT (approval)--plunger valves.
 - o Central Utah Water Conservancy District, UT (approval)--double offset butterfly valves.
 - SRF COVID-19 Qs & As for state and regional SRF programs (jointly with CWSRF).

To: Fuld, John [Fuld.John@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov];

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Subject: Bi-Weekly w/OGWDW

Attachments: OGWDW Bi-Weekly Agenda with OW Sr. Leadership_05152020_v1.docx

Location: Call in Ex. 6 Personal Privacy (PP)

Start: 5/15/2020 2:00:00 PM **End**: 5/15/2020 2:30:00 PM

Show Time As: Busy

Recurrence: (none)

every 2 week(s) on Wednesday from 4:00 PM to 4:45 PM

Attendee list adjusted to be OGWDW OD, DOD, and Special Assistant only.

OGWDW Bi-Weekly with OW Senior Leadership

May 15, 2020

Agenda

- Lead Free Rule (Awareness)
- Perchlorate (Awareness)
- Lead and Coper Rule (Awareness)
- GAO & OIG audits (Awareness)
- COVID (Awareness)
- Feedback from SLC MYP discussion? (Awareness)

Actions in OW-IO for Input

- Section 1459A Grants Briefing Follow-up Next steps
 - OW briefing March 10, 2020. OW indicated the need for senior level discussions regarding certain aspects of the statutory language. OGWDW requests input on those discussions and decisions outlined in briefing to move forward with the grant development and to formulate the option selection briefing for the next set of OW decisions needed for the construct of the grant program.

Upcoming External Engagements/Document Release Info/Events

5/12	Posting: Recording of AWIA Workshop for Small and Medium Systems
5/12	Posting: Checklist for Small Community Water System Risk and Resilience Assessments
5/20	Webinar: Water Contaminant Information Tool (WCIT) Webinar
5/20	Posting: UIC Data Application User's Manual

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Summary of Items for Awareness

<u>Lead Free Rule</u>: EPA (OGWDW & NCEE) and OMB staff agreed upon an approach to address the

Ex. 5 Deliberative Process (DP)

• <u>Perchlorate</u>: Final Agency Review took place on May 7, 2020. All participating offices concurred and three (OP, OGC, and OCHP) concurred with comment. OGWDW is incorporating the edits and addressing the majority of the recommendations provided by OP and OGC, the key exception being

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP) OGWDW will be providing a revised FRN for OW soon so that we can transmit to OMB for their review. The consent decree deadline is June 19, 2020.

<u>Lead and Copper Rule</u>: OGWDW is preparing an options paper on
 Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

- GAO & OIG audits: OGWDW has a high number of audit related activities, including meetings, questions and information/data requests, notifications of new engagements, requests for responses to draft and final reports, and status updates on and documentation of open recommendations and corrective actions. Since March, we've received over 150 GAO/OIG related emails.
 - Lead in Child Care Facilities (103241)
 - Monitoring and Oversight of Response to Coronavirus 2019 Pandemic (104237)
 - Lead and Copper Rule Requirements (103512)
 - Engagement on IRIS Program (103997)
 - Chemical Facility Anti-Terrorism Standards and Regulation (103866 and 103806)
 - Chemical Contamination by PFAS (JC 103982)
 - Regulation of Private Water Rates (104163)
 - Chemical Prog. Data Reliability Qs (103806/104086)
 - Cybersecurity Framework Impact (103316)
 - Water Infrastructure: Technical Assistance and Climate Resilience Planning Could Help Utilities Prepare for Potential Climate Change Impacts

- Airline Food Safety and Sanitation (103469)
- Cybersecurity Leadership and Strategy (103164)
- Critical Infrastructure Protection: Additional Actions Needed to Identify Framework Adoption and Resulting Improvements (GAO-20-299)
- OIG: Effects of Coronavirus Pandemic (SARS-CoV-2 Virus and COVID-19 Disease) on EPA Programs and Operations (OA&E-FY20-0212)
- OIG: EPA Must Improve Oversight of Notice to the Public on Drinking Water Risks to Better Protect Human (19-P00318-168)
- OIG: Audit of Select Rulemakings
- OIG: Effectiveness of Clean Water Act to Protect from Plastic Pollution

Attachments for Items for Decision

N/A

[PAGE * MERGEFORMAT]

To:

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Braschayko, Kelley [braschayko.kelley@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; Risley, David

[Risley.David@epa.gov]

Subject: Bi-Weekly w/OGWDW

Attachments: OGWDW.Bi-Weekly. Agenda with ΩW.Sr. Leadership_05272020_FINAL.docx

Location: Call in Ex. 6 Personal Privacy (PP)

Start: 5/27/2020 3:30:00 PM **End**: 5/27/2020 4:00:00 PM

Show Time As: Busy

Recurrence: (none)

every 2 week(s) on Wednesday from 4:00 PM to 4:45 PM

Attendee list adjusted to be OGWDW OD, DOD, and Special Assistant only.

OGWDW Bi-Weekly with OW Senior Leadership

May 27, 2020

Agenda

- Lead Free Rule (Awareness)
- Perchlorate (Awareness)
- Lead and Coper Rule (Awareness)
- AWWA Drinking Water Affordability Panel (Awareness)
- National Drinking Water Advisory Council (Awareness)
- Six-Year Review 4 Request for Data from Primacy Agencies (Awareness)
- Guidance Document Review Process

Actions in OW-IO for Input

- Section 1459A Grants Decisions
- COVID-19 Flexibilities and Priorities FAQ
- Tribal COVID Resources website
- Awards to ASDWA Under Public Interest Exception (coming soon for OW-IO review/approval)

Upcoming External Engagements/Document Release Info/Events

5/20	Webinar. AIS Lunch and Learn refresher webinar on stainless steel nuts and bolts. Participants: states, borrowers, manufacturers, distributers.
5/26	Staff presentation. International online workshop on Vulnerability and Resilience of the Water Infrastructure sponsored by the World Federation of Scientists.
5/29	Staff presentation on AWIA. Virtual - Joint American Military Engineers (SAME) and Engineer Training Conference.
6/2	Support Documents. Capacity Development Coordinator Handbook and Operator Certification Coordinator Handbook.
6/2	Webinar. COVID-19: Water System Re-entry and Returning to "Normal" Operations.
6/4	Support Tools. Metadata Best Practices and Internet Factsheet, 2019 Program Collaboration Resource List, Updated Tabletop Exercise.

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Lead Free Rule: OGWDW and OGC discussed approaches to exempting

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

• Perchlorate: The Final Perchlorate Action was transmitted to OP on May 21, 2020 for transmission to OMB. As of May 26, 2019,

Ex. 5 Deliberative Process (DP)

Lead and Copper Rule: On May 22. QGWDW provided a revised issue paper to QW providing provide options for Ex. 5 Deliberative Process (DP).

Ex. 5 Deliberative Process (DP)

- AWWA Drinking Water Affordability Work Group: The American Water Works Association held a kickoff of their Affordability Work Group on May 22, 2019. The Work Group chairs, Dr. John Graham (Indiana University) and Dr. Cary Coglianese (University of Pennsylvania) participated in the discussion. The purpose of the workgroup is to "Identify analytical approaches the United States Environmental Protection Agency could productively pursue in order to consider the affordability of water service in making regulatory decisions under the Safe Drinking Water Act. Effective analysis of affordability can be informative in selecting an appropriate rule option." AWWA's goal is to provide a report to EPA by January 2021. EPA staff from OGWDW, OWM, and NCEE participated. EPA representatives stated that they were participating as technical resources to the group and explained that EPA would not be developing or agreeing to any recommendations made by the group.
- National Drinking Water Advisory Council: OGWDW is preparing to publish a 30-day notice, signed by the Office Director, in the Federal Register in June to solicit nominations to fill five vacancies that will occur in December 2020 on the National Drinking Advisory Council (NDWAC). Concurrent with the Federal Register solicitation and in keeping with standard Agency practice, the AA for Water will send a memo to EPA's Assistant Administrators and Regional Administrators inviting them to submit nominations. OGWDW will also conduct outreach to water sector organizations. In July, OGWDW will provide a slate of qualified candidates (five recommended and two alternate candidates) to OW for review and AA concurrence. OGWDW will then send the slate to the Administrator's Office for review. Each selected candidate will receive an invitation letter from the Administrator to serve on the NDWAC for a three-year term starting in December 2020. In addition to the five new members, OGWDW is proposing reappointments for four current NDWAC members, all of whom were appointed by the Administrator in FY 2018. OGWDW will also propose a new chairperson, likely from the current members.
- <u>Data Call 6-Year Review</u>: OGWDW plans to send letters to all primacy agencies requesting voluntary submission of contaminant occurrence data and treatment technique information for regulated contaminants. EPA is encouraging primacy agencies to submit their data to improve EPA's understanding of regulated contaminants in drinking water and help decide whether existing regulations need to be revised. These data help EPA decide whether existing regulations are protecting public health and to identify whether any of the regulations need to be revised. This collection of data has been approved by the Office of Management and Budget.

Attachments for Items for Decision

N/A

[PAGE * MERGEFORMAT]

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Subject: Bi-Weekly w/OGWDW

Attachments: OGWDW Bi-Weekly Agenda with OW Sr. Leadership_06092020.docx

Location: Call in Ex. 5 Deliberative Process (DP)

Start: 6/9/2020 3:30:00 PM **End**: 6/9/2020 4:00:00 PM

Show Time As: Busy

Recurrence: (none)

every 2 week(s) on Wednesday from 4:00 PM to 4:45 PM

Attendee list adjusted to be OGWDW OD, DOD, and Special Assistant only.

OGWDW Bi-Weekly with OW Senior Leadership

June 9, 2020

Agenda

- Lead Free Rule (Awareness)
- Perchlorate (Awareness)
- Lead and Coper Rule (Awareness)
- Proposed Revisions to the Unregulated Contaminant Monitoring Rule (UCMR 5) for Public Water Systems and Announcement of Public Meeting (Awareness)
- Hurricane Season (Awareness)
- Additional Supplemental Appropriations for Disaster Relief Act, 2019 Alaska Funds (Awareness)
- Draft Interim Guidance on Destruction and Disposal of PFAS (Awareness)
- Drinking Water Infrastructure Needs Survey Information Collection Request (Awareness)

Actions in OW-IO for Input

- Tribal COVID Resources Website
- WH Request on Chemical Supply Chain
- Potential Executive Order for Water Sector
- Existing Flexibilities in Drinking Water Laboratory Certification Program Oversight Responsibilities
- ECOS PFAS presentation

Upcoming External Engagements/Document Release Info/Events

6/8	Webinar. Re-entry and Return to Normal Operations
6/9	Meeting. Water Sector Best Practices in Sustaining Operations During COVID-19 Response
6/10	Webinar. AWWA Returning to Service: Addressing Water Quality in Buildings with Low or No Use
6/29	Meeting: ECOS-EPA Bimonthly PFAS Call
6/15:	Webinar. Overview of Federal Disaster and Mitigation Funding Programs as related to COVID-19, hosted by the Water Security Division
6/16	Briefing. Community Water Systems out of compliance Metric (with Henry Darwin)
6/24:	Webinar. AIS "Lunch and Learn" Refresher Webinar on the National De Minimis Waiver

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Deliberative – For internal use **Summary of Items for Awareness**

• <u>Lead Free Rule</u>: OGWDW has revised the FR Notice, Technical Support Document and Response to Comment document. We expect to have the documents for OW review this week.

•	<u>Perchlorate</u> : OMB facilitated verbal comments from DOJ and transmitted Inter-Agency written comments on
	the draft Final Action from OMB, USDA, SBA, and EOP on June 4 and 5. OGWDW has drafted responses. The
	most significant issues on which we disagree are § Ex. 5 Deliberative Process (DP)
	Ex. 5 Deliberative Process (DP)
	Ex. 5 Deliberative Process (DP)
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	Ex. 5 Deliberative Process (DP) We hope to transmit the response to OMB today or tomorrow
	(following OW review). The consent decree deadline is June 19, 2020 and DOJ has requested signature not
	later than June 18, 2020 (preferably earlier).
,	Lead and Copper Rule Revisions: On June 8, OW met with the Administrator regarding options [Ex. 5 Deliberative Process (DP)]
	Economic Copper Nate Newsons. Of Surface of Own free With the Administrates regarding options [23:35:66:67:67:67:76:76:76:76:76:76:76:76:76:
	Ex. 5 Deliberative Process (DP)
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- <u>Unregulated Contaminant Monitoring Rule:</u> OGWDW has prepared the draft proposal for the UCMR 5 in accordance with option selection decisions earlier this year. The proposed UCMR 5 would require monitoring for 29 PFAS (consistent with the PFAS Action plan and the NDAA) and lithium. All systems serving more than 3,300 people and a representative sample of smaller water systems would be required to perform monitoring (consistent with the AWIA requirements), increasing by eight-fold the number of small water systems that the EPA would be responsible for performing the laboratory analysis. The draft proposal takes comment on reducing the scope of the monitoring for small systems if there are not sufficient appropriations for the EPA to pay this cost. The draft proposal also takes comment on monitoring other contaminants including legionella and disinfection byproducts. OGWDW plans to transmit this proposal for OW review prior to Inter-Agency review this week. EPA stated in the PFAS Action Plan that we will propose the UCMR 5 in 2020, OGWDW is targeting final signature by October 2020.
- OW HQ Response Posture for Hurricane Season 2020: The 2020 hurricane season is predicted to be very active. During large-scale disaster responses impacting multiple states or multiple EPA regions, OW manages the Water Desk within the Planning Section of the HQ Emergency Operations Center (EOC). Additionally, FEMA may request an EPA Water Subject Matter Expert (SME) to serve with the US Army Corps of Engineers (USACE) at the Emergency Support Function #3 (ESF-3) Desk in the National Response Coordination Center (NRCC). EPA's role is largely the same at both the HQ EOC and the NRCC: collect information about the operating status of the water sector (i.e, Common Operating Picture), identify issues that could impact utilities' return to full service, coordinate issue resolution, and convey information to senior leaders and others. OW has a robust staff of experienced emergency managers who can fulfill these functions, starting with WSD's Emergency Response

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Team. Should the need to perform these functions extend beyond a few weeks, OW has a cadre of 40 trained Response Support Corps (RSC) members who can also serve in these roles. WSD developed a draft NRCC ESF-3 Water Desk Guide to outline expectations, roles, and responsibilities, and also updated the EPA EOC Water Desk User's Guide in advance of the 2020 hurricane season.

- ESF#3 Water Mission Assignments Activities Related to Hurricane Season 2020: WSD has had ongoing discussions with FEMA regarding execution of water missions through ESF-3, where primary aspects of water sector response reside, versus ESF-10, which focuses on hazardous material and oil spill response. EPA conducted a coordination call with HQ FEMA and US Army Corps of Engineers (USACE) on May 28, 2020 during which FEMA reaffirmed their intention to issue water missions assignments through ESF-3, and to communicate this process to their FEMA Regions. OW coordinates closely with the OEM to ensure disaster response are managed efficiently and effectively under OneEPA. This includes agreement to develop consistent HQ and Regional procedures for managing water missions under ESF-3. WSD and OEM met with the Regional Water Team Leads and Emergency Program staff in Regions 2, 3, 4 and 6 on June 5, 2020 to discuss hurricane season preparedness and the assignment of e water missions under ESF-3. Similar calls with the remaining EPA Regions will be scheduled soon.
- EPA-FEMA-USACE Memo: The National Security Council, in an October 24, 2019 letter, requested that the Emergency Support Function Leadership Group (ESFLG) establish a workgroup to propose methods for addressing improved Water Sector integration into the NRF. Subsequently, a Preparedness, Evaluation and Corrective Actions Workgroup (PECAWG) was formed and met four times on this topic until discussions were interrupted in March 2020 by the coronavirus pandemic. With the approach of hurricane season and a high likelihood of hurricane-related water sector impacts requiring federal response, WSD drafted a Memo for FEMA, EPA and USACE to serve as interim guidance, effectively a high level SOP, until the PECAWG process can be completed. This memorandum outlines accepted immediate process improvements for federal water sector response based on conversations with the FEMA, USACE and EPA. The Memo states that FEMA mission assignments for water infrastructure assessment and response should be directed to ESF-3, either via USACE as the ESF-3 coordinator, or directly to the EPA, in close coordination with USACE. The draft Memo has been shared with FEMA, USACE as well as all EPA Regions; comments are requested by June 11, 2020.
- Tropical Storm (TS) Cristobal: On June 5, WSD coordinated with the NRCC before TS Cristobal made landfall to obtain access to their WebEOC system for virtual staffing should the NRCC Water SME position be activated. WSD shared Water Desk staffing plans with the EPA HQ EOC for potential activation during TS Cristobal. On June 8, WSD reached out to Regions 6 and 4 after landfall of TS Cristobal no water system impacts are reported at this time. WSD will reach out on June 9 to Regions 6 and 7.
- Additional Supplemental Appropriations for Disaster Relief Act, 2019: Alaska funds: On June 6, 2019, the President signed P.L. 116-20, the "Additional Supplemental Appropriations for Disaster Relief Act, 2019" (ASADRA), into law. The EPA section of the ASADRA includes \$349.4 million in supplemental funding for the State Revolving Fund (SRF) programs: \$53.3 million for Clean Water State Revolving Fund (CWSRF) and \$296.1 million for Drinking Water State Revolving Fund (DWSRF), available only to states or territories in EPA Regions 4, 9, and 10 for wastewater treatment works and drinking water facilities impacted by Hurricanes Florence and Michael, Typhoon Yutu, and calendar year 2018 wildfires and earthquakes. Alaska, and specifically the City of Anchorage, is ASADRA-eligible because the City was hit by a magnitude 7.0 earthquake in calendar year 2018. On October 23, 2019, EPA HQ notified EPA Region 10 that Alaska's ASADRA supplemental allotment is \$376,000 for the CWSRF program and \$26,272,000 for the DWSRF program. Based on this amount of funding, the state must provide a 20% match equaling \$75,200 for the CWSRF funds and \$5,254,400 for the DWSRF funds. The Alaska Department of Environmental Conservation has indicated an intent to not apply for and receive its

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ASADRA grant due to its inability to provide the 20 percent match requirement and insufficient project demand. If Alaska does not apply for the funds by the deadline, EPA must reallot the ASADRA funds among eligible recipients^[1] after the end of the fiscal year.

- <u>Draft Interim Guidance on the Destruction and Disposal of PFAS materials</u>: The National Defense Acquisition Act tasks the Agency with development of an Interim Guidance on the Destruction and Disposal of PFAS materials. OSRTI is leading a workgroup of eight offices, which includes OW (OGWDW and OST). The report focuses on three technologies to manage the destruction and disposal of PFAS materials. OGWDW actively participated in the development of the technology section on the use of Class I injection wells to manage the disposal of PFAS material and in reviewing the interim guidance, in particular, the destruction and disposal of PFAS waste from drinking water treatment. We expect that the OW AA will receive a draft as early as the end of this week and as late as next week. OLEM is planning on submitting the guidance to OP on June 24th to start interagency review by July 2nd.
- Needs Survey: OGWDW plans to announce EPA's intent to forward the information collection request (ICR) for the 2020 Drinking Water Infrastructure Needs Survey to the Office of Management and Budget for approval. The agency's notice is also announcing an additional 30 days for public comment. In the first 30-day comment period, OGWDW received comments from the American Water Works Association, the Academy of Nutrition and Dietetics, and the National Ground Water Association. While the public input did not change the ICR burden estimate, specific recommendations for improving the clarity and communications resulted in changes to the Survey's questionnaire, instructions, and planned training sessions.

Attachments for Items for Decision

N/A

^[1] Section §300j-12 (a)(1)(E) of the Safe Drinking Water Act (SDWA) and Section 1256. (g) of the Clean Water Act (CWA) authorizes capitalization grant reallotments.

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Sent: 8/5/2019 2:07:03 PM

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Subject: Bi-Weekly w/OGWDW

Attachments: Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) Untitled Attachment; Untitled

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Ex. 6 Personal Privacy (PP)

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Location: Ex. 6 Personal Privacy (PP)

Start: 7/29/2020 3:00:00 PM **End**: 7/29/2020 3:45:00 PM

Show Time As: Tentative

Recurrence: Weekly

every 2 week(s) on Wednesday from 11:00 AM to 11:45 AM

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w/OGWDW

Location: 3233 WJCE

Start: 5/1/2019 8:00:00 PM **End**: 5/1/2019 8:45:00 PM

Show Time As: Tentative

Recurrence: Weekly

Occurs on Wednesday every other week from 4:00 PM to 4:45 PM effective 5/1/2019.

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Attachments: OGWDW Biweekly_100919.docx

Location: 3233 WJCE

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Show Time As: Busy

Fuld, John [Fuld.John@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Thompkins, Anita [Thompkins.Anita@epa.gov]; Travers, David [Travers.David@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Tovar, Katlyn [tovar.katlyn@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; McLain, Jennifer L. [Mclain.Jennifer@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Owscheduling [Owscheduling@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; McLain, Jennifer L. [Mclain.Jennifer@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-

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Subject: Bi-Weekly w/OGWDW

Attachments: OGWDW Bi-Weekly Agenda with OW Sr. Leadership 06242020 FINAL.docx

Location: Ex. 6 Personal Privacy (PP)

6/24/2020 2:30:00 PM Start: 6/24/2020 3:00:00 PM

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Recurrence: (none)

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Attachment

Location: 3233 WJCE

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Subject: Attachments: Brownbag -Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP)

OGWDW Bi-Weekly_03112020_v1.docx \(\frac{1}{2}\) Location:

3233 WJCE

Start: 3/11/2020 4:15:00 PM End: 3/11/2020 5:00:00 PM

Show Time As: Busy

Recurrence: (none)

Sent: 8/5/2019 2:07:03 PM

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; McLain, Jennifer L.

[McLain.Jennifer@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; Tiago, Joseph

[Tiago.Joseph@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Mejias,

Melissa [mejias.melissa@epa.gov]; Tovar, Katlyn [tovar.katlyn@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Travers, David

[Travers.David@epa.gov]; Thompkins, Anita [Thompkins.Anita@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov];

Spraul, Greg [Spraul.Greg@epa.gov]; Fuld, John [Fuld.John@epa.gov]

CC: Lousberg, Macara [Lousberg.Macara@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Risley, David

[Risley.David@epa.gov]; Gordon, Brittney [Gordon.Brittney@epa.gov]; Klein, Melissa [Klein.Melissa@epa.gov]

Subject: Bi-Weekly w/OGWDW

Attachments: Untitled Attachment; Bi-Weekly w/OGWDW Call ir Ex. 6 Personal Privacy (PP) Untitled Attachment; Untit

Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Brownbag -Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP)

Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP); Untitled Attachment; Unt

Weekly w/OGWDW; Untitled Attachment; Untitled Attachment; Bi-Weekly w/OGWDW; Untitled Attachment;

Untitled Attachment: Untitled Attachment

Location: Call in Ex. 6 Personal Privacy (PP)

Start: 7/29/2020 3:00:00 PM **End**: 7/29/2020 3:45:00 PM

Show Time As: Tentative

Recurrence: Weekly

Sent: 8/5/2019 2:07:03 PM

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; McLain, Jennifer L.

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[Risley. David@epa.gov]; Gordon, Brittney [Gordon. Brittney@epa.gov]; Klein, Melissa [Klein. Melissa@epa.gov]

Subject: Bi-Weekly w/OGWDW

Attachments: Untitled Attachment; Bi-Weekly w/OGWDW Call ir Ex. 6 Personal Privacy (PP) ; Untitled Attachment; Untitled

Attachment; Untitled Attachmen

Weekly w/OGWDW; Untitled Attachment; Untitled Attachment; Bi-Weekly w/OGWDW; Untitled Attachment;

Untitled Attachment; Untitled Attachment

Location: Call in Ex. 6 Personal Privacy (PP)

Start: 7/29/2020 3:00:00 PM **End**: 7/29/2020 3:45:00 PM

Show Time As: Tentative

Recurrence: Weekly

Fuld, John [Fuld.John@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Thompkins, Anita [Thompkins.Anita@epa.gov]; Travers, David [Travers.David@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Tovar, Katlyn [tovar.katlyn@epa.gov]; Dennis, Allison [Dennis.Allison@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Forsgren, Lee

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[Mclain.Jennifer@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]

CC: Klein, Melissa [Klein.Melissa@epa.gov]; Gordon, Brittney [Gordon.Brittney@epa.gov]; Risley, David

[Risley.David@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Lousberg, Macara

[Lousberg.Macara@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; Risley, David [Risley.David@epa.gov]; Tovar, Katlyn [tovar.katlyn@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]

Subject: Bi-Weekly w/OGWDW

Attachments: OGWDW Biweekly_Agenda_04302020.docx
Location: Call in Ex. 6 Personal Privacy (PP)

Start: 4/30/2020 7:30:00 PM **End**: 4/30/2020 8:00:00 PM

Show Time As: Busy

Recurrence: (none)

every 2 week(s) on Wednesday from 4:00 PM to 4:45 PM

Fuld, John [Fuld.John@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Thompkins, Anita [Thompkins.Anita@epa.gov]; Travers, David [Travers.David@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Tovar, Katlyn [tovar.katlyn@epa.gov]; Dennis, Allison [Dennis.Allison@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; McLain, Jennifer L. [Mclain.Jennifer@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; McLain, Jennifer L. [Mclain.Jennifer@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Dennis, Allison [Dennis.Allison@epa.gov]; Tovar, Katlyn [tovar.katlyn@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Travers, David [Travers.David@epa.gov]; Thompkins, Anita [Thompkins.Anita@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Fuld, John [Fuld.John@epa.gov]; Campbell, Ann [Campbell.Ann@epa.gov] Macara Lousberg [Lousberg.Macara@epa.gov]; Klein, Melissa [Klein.Melissa@epa.gov]; Gordon, Brittney

CC:

[Gordon.Brittney@epa.gov]; Risley, David [Risley.David@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Lousberg, Macara [Lousberg.Macara@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Risley, David [Risley.David@epa.gov]; Klein, Melissa [Klein.Melissa@epa.gov]

Subject: Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP)

Attachments: OGWDW Bi-Weekly_02112020_v1.docx

Start: 2/12/2020 3:00:00 PM **End**: 2/12/2020 3:30:00 PM

Show Time As: Busy

Recurrence: (none)

To: Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov];

Newberry, Debbie [Newberry.Debbie@epa.gov]; McLain, Jennifer L. [Mclain.Jennifer@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Aguirre, Janita

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John [Fuld.John@epa.gov]; Owscheduling [Owscheduling@epa.gov]; Bertrand, Charlotte

[Bertrand.Charlotte@epa.gov]; Campbell, Ann [Campbell.Ann@epa.gov]

CC: Macara Lousberg [Lousberg.Macara@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Risley, David

[Risley.David@epa.gov]; Gordon, Brittney [Gordon.Brittney@epa.gov]; Klein, Melissa [Klein.Melissa@epa.gov];

Lousberg, Macara [Lousberg.Macara@epa.gov]

Subject: Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP)

Attachments: OGWDW Bi-Weekly_02262020.docx

Start: 2/26/2020 3:00:00 PM **End**: 2/26/2020 3:45:00 PM

Show Time As: Busy

Recurrence: (none)

Fuld, John [Fuld.John@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Thompkins, Anita [Thompkins.Anita@epa.gov]; Travers, David [Travers.David@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Tovar, Katlyn [tovar.katlyn@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Fuld, John [Fuld.John@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Thompkins, Anita [Thompkins.Anita@epa.gov]; Travers, David [Travers.David@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Tovar, Katlyn [tovar.katlyn@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; McLain, Jennifer L. [McLain.Jennifer@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Owscheduling [Owscheduling@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; McLain, Jennifer L. [Mclain.Jennifer@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]

CC:

Klein, Melissa [Klein.Melissa@epa.gov]; Gordon, Brittney [Gordon.Brittney@epa.gov]; Klein, Melissa [Klein.Melissa@epa.gov]; Gordon, Brittney [Gordon.Brittney@epa.gov]; Risley, David [Risley.David@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Lousberg, Macara [Lousberg.Macara@epa.gov]; Risley, David [Risley.David@epa.gov]; Lousberg, Macara [Lousberg.Macara@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Braschayko, Kelley [braschayko.kelley@epa.gov]

Subject: Bi-Weekly w/OGWDW

Attachments: OGWDW Bi-Weekly Agenda with OW Sr. Leadership_06092020.docx

Location: Call in Ex. 6 Personal Privacy (PP)

Start: 6/9/2020 3:30:00 PM End: 6/9/2020 4:00:00 PM

Show Time As: Busy

Recurrence: (none)

every 2 week(s) on Wednesday from 4:00 PM to 4:45 PM

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; Mclain, Jennifer

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[Guilaran.Yu-Ting@epa.gov]; Risley, David [Risley.David@epa.gov]; Gordon, Brittney [Gordon.Brittney@epa.gov];

Klein, Melissa [Klein.Melissa@epa.gov]

Attachments: OGWDW Bi-Weekly_111419.docx

Location: 3233 WJCE

Start: 11/14/2019 4:00:00 PM **End**: 11/14/2019 4:30:00 PM

Show Time As: Busy

CC:

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; Mclain, Jennifer

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[Guilaran.Yu-Ting@epa.gov]; Risley, David [Risley.David@epa.gov]

Attachments: OGWDW Biweekly_091319.docx; Perchlorate Comment Summary V4.pdf; Copy of LCR Revisions Proposal Schedule

9-12-19.pdf

Location: 3233 WJCE

Start: 9/13/2019 3:00:00 PM **End**: 9/13/2019 3:45:00 PM

Show Time As: Busy

CC:

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

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Macara Lousberg [Lousberg.Macara@epa.gov]; Lousberg, Macara [Lousberg.Macara@epa.gov]; Guilaran, Yu-Ting

[Guilaran.Yu-Ting@epa.gov]; Risley, David [Risley.David@epa.gov]

Attachments: OGWDW Biweekly_091319.docx; Perchlorate Comment Summary V4.pdf; Copy of LCR Revisions Proposal Schedule

9-12-19.pdf

Location: 3233 WJCE

Start: 9/13/2019 3:00:00 PM **End**: 9/13/2019 3:45:00 PM

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Campbell, Ann [Campbell.Ann@epa.gov]

CC: Macara Lousberg [Lousberg.Macara@epa.gov]; Lousberg, Macara [Lousberg.Macara@epa.gov]; Guilaran, Yu-Ting

[Guilaran.Yu-Ting@epa.gov]; Risley, David [Risley.David@epa.gov]; Gordon, Brittney [Gordon.Brittney@epa.gov];

Klein, Melissa [Klein.Melissa@epa.gov]

Attachments: OGWDW Bi-Weekly_103119.docx

Location: 3233 WJCE

Start: 10/31/2019 2:30:00 PM **End**: 10/31/2019 3:00:00 PM

Show Time As: Busy

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; Mclain, Jennifer

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Klein, Melissa [Klein.Melissa@epa.gov]

Attachments: OGWDW Bi-Weekly_111419.docx

Location: 3233 WJCE

Start: 11/14/2019 4:00:00 PM **End**: 11/14/2019 4:30:00 PM

Show Time As: Busy

Sent: 8/5/2019 2:07:03 PM

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; McLain, Jennifer L.

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CC: Lousberg, Macara [Lousberg.Macara@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Risley, David

[Risley.David@epa.gov]

Subject: Bi-Weekly w/OGWDW

Attachments: Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP); Untitled Attachment; Untitled

Ex. 6 Personal Privacy (PP) 2; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Untitled Attachment; Untitled Attachment; Bi-Weekly w/OGWDW; Untitled Attachment; Untitled Attachment; Bi-Weekly w/OGWDW; Untitled Attachment; Untitled Attachment; Canceled: Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) ; Untitled Attachment; Bi-Weekly

w/OGWDW; Untitled Attachment; Untitled Attachment

Location: Call in Ex. 6 Personal Privacy (PP)

Start: 8/6/2020 8:00:00 PM **End**: 8/6/2020 8:45:00 PM

Show Time As: Busy

Recurrence: Weekly

every Thursday from 4:00 PM to 4:45 PM

Fuld, John [Fuld.John@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Thompkins, Anita [Thompkins.Anita@epa.gov]; Travers, David [Travers.David@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; McLain, Jennifer L. [Mclain.Jennifer@epa.gov]; Fuld, John [Fuld.John@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Thompkins, Anita [Thompkins.Anita@epa.gov]; Travers, David [Travers.David@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; McLain, Jennifer L. [Mclain.Jennifer@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Owscheduling [Owscheduling@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; McLain, Jennifer L. [Mclain.Jennifer@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Campbell, Ann [Campbell.Ann@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov] Lousberg, Macara [Lousberg.Macara@epa.gov]; Risley, David [Risley.David@epa.gov]; Risley, David

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Attachments: OGWDW Bi-Weekly Agenda with OW Sr. Leadership_08072020.docx; A1 - Memo - SRF Reallotment

Procedures.v5_8-4-2020.docx; A2 - FY2019 Reallotment Procedure Memo Attachment A_v2_8-4-2020.docx; A3 -

Reallotment Attachment B.pdf; A4 - Reallotment Attachment C.pdf

Start: 8/7/2020 7:00:00 PM **End**: 8/7/2020 7:45:00 PM

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Recurrence: (none)

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Subject: Bi-Weekly w/OGWDW

Attachments: Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) Untitled Attachment; Untitled

Attachment; Untitled Attachmen

Weekly w/OGWDW; Untitled Attachment; Untitled Attachment; Bi-Weekly w/OGWDW; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Canceled: Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) Untitled Attachment; Bi-Weekly

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Location: Call in Ex. 6 Personal Privacy (PP)

Start: 8/6/2020 8:00:00 PM **End**: 8/6/2020 8:45:00 PM

Show Time As: Busy

Recurrence: Weekly

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Braschayko, Kelley [braschayko.kelley@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; Risley, David

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Subject: Bi-Weekly w/OGWDW

Attachments: OGWDW Bi-Weekly Agenda with OW Sr. Leadership_05272020_FINAL.docx

Location: Call in Ex. 6 Personal Privacy (PP)

Start: 5/27/2020 3:30:00 PM **End**: 5/27/2020 4:00:00 PM

Show Time As: Busy

Recurrence: (none)

every 2 week(s) on Wednesday from 4:00 PM to 4:45 PM

CC:

To: Fuld, John [Fuld.John@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Thompkins, Anita

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Reallotment Attachment B.pdf; A4 - Reallotment Attachment C.pdf

Location: Call in Ex. 6 Personal Privacy (PP)

Start: 8/7/2020 7:00:00 PM **End**: 8/7/2020 7:45:00 PM

Show Time As: Busy

Recurrence: (none)

To: Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov];

Mason, Paula [Mason.Paula@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Dennis, Allison [Dennis.Allison@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Travers, David [Travers.David@epa.gov];

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Subject: Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP)

Attachments: OGWDW Biweekly_Agenda_04142020.docx

Location: 2029910477, 1300632#

Start: 4/14/2020 7:30:00 PM **End**: 4/14/2020 8:00:00 PM

Show Time As: Busy

Recurrence: (none)

every 2 week(s) on Wednesday from 4:00 PM to 4:45 PM

OGWDW Bi-Weekly with OW April 14, 2020

Agenda

- Lead and Coper Rule Revisions
- Lead Free OMB Pass Back
- COVID-19
 - o Chemical Supply Chain Issues
 - FEMA Public Assistance Funding
- Perchlorate FRN Final Agency Review
- Cybersecurity "Tiger Team"

OGWDW Actions in OW-IO for Input

- COVID-19 Tribal Water Utility Template
- COVID-19 Implications for Drinking Water and Clean Water Programs
- Prioritization of Water Sector Employee Testing and PPE Distribution during COVID-19 Letter from Administrator Wheeler to Secretary Azar
- OGWDW Workplan and disinvestment Follow-up
 - ⊙ Ex. 5 Deliberative Process (DP)
- America's Water Sector Workforce Initiative: A Call to Action
 - o Includes Email to Federal Partners Seeking Concurrence to Publish the FRN
- Section 1459A Grants Briefing Follow-up Next steps
 - We briefed Dave, Charlotte and Lee- a few weeks ago and need to know what else do they need to make decisions and for us to move forward

Heads Up

- UIC Program at-a-Glance Fact Sheet.
- Flushing Guidance for Resuming/Initiating Service at Larger Buildings Under Development.
- Federal Resources for Tribal Communities.

External engagements/document release info:

- 4/9 Meeting. Sustainable Systems Staff monthly meeting with ASDWA.
- 4/9 GWPC Selection for the FY20 UIC and Source Water Competitive Grant sent to OGD.
- 4/14 Meeting. Quarterly with NGOs.
- 4/14 Webinar. EPA's Pandemic Incident Action Checklist with Tribal Water and Wastewater Utilities.
- 4/15 Announcement. SDWIS Modernization Board formation (communication approved by OW on 3/18) shared today by ASDWA and ECOS to their communities.
- 4/16 Meeting. Virtual SRF State-EPA Workgroup.

4/20 Memorandum.

- AIS Waiver Request Decision Memorandum:
 - o Central Utah Water Conservancy District, UT (approval)--plunger valves.
 - o Central Utah Water Conservancy District, UT (approval)--double offset butterfly valves.
- SRF COVID-19 Qs & As for state and regional SRF programs (jointly with CWSRF).

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Attachments: OGWDW Bi-Weekly_103119.docx

Location: 3233 WJCE

Start: 10/31/2019 2:30:00 PM **End**: 10/31/2019 3:00:00 PM

Show Time As: Busy

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Subject: Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP)

Attachments: OGWDW Bi-Weekly_02262020.docx

Start: 2/26/2020 3:00:00 PM **End**: 2/26/2020 3:45:00 PM

Show Time As: Busy

Recurrence: (none)

Fuld, John [Fuld.John@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Thompkins, Anita [Thompkins.Anita@epa.gov]; Travers, David [Travers.David@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Tovar, Katlyn [tovar.katlyn@epa.gov]; Dennis, Allison [Dennis.Allison@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; McLain, Jennifer L. [Mclain.Jennifer@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; McLain, Jennifer L. [Mclain.Jennifer@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Dennis, Allison [Dennis.Allison@epa.gov]; Tovar, Katlyn [tovar.katlyn@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Travers, David [Travers.David@epa.gov]; Thompkins, Anita [Thompkins.Anita@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Fuld, John [Fuld.John@epa.gov]; Campbell, Ann [Campbell.Ann@epa.gov] Macara Lousberg [Lousberg.Macara@epa.gov]; Klein, Melissa [Klein.Melissa@epa.gov]; Gordon, Brittney [Gordon.Brittney@epa.gov]; Risley, David [Risley.David@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov];

CC:

[Gordon.Brittney@epa.gov]; Risley, David [Risley.David@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Lousberg, Macara [Lousberg.Macara@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Risley, David [Risley.David@epa.gov]; Gordon, Brittney [Gordon.Brittney@epa.gov]; Klein, Melissa [Klein.Melissa@epa.gov]

Subject: Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP)

Attachments: OGWDW Bi-Weekly_02112020_v1.docx

Start: 2/12/2020 3:00:00 PM **End**: 2/12/2020 3:30:00 PM

Show Time As: Busy

Recurrence: (none)

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; Mclain, Jennifer

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[Guilaran. Yu-Ting@epa.gov]; Risley, David [Risley. David@epa.gov]; Gordon, Brittney [Gordon. Brittney@epa.gov]; Risley, David@epa.gov]; Gordon, Brittney [Gordon. Brittney@epa.gov]; Risley, David [Risley. David@epa.gov]; Gordon, Brittney [Gordon. Brittney@epa.gov]; Gordon, Brittney [Gordon. Brittney@epa.gov]; Gordon, Brittney [Gordon. Brittney@epa.gov]; Gordon, Brittney [Gordon. Brittney@epa.gov]; Gordon, Gor

Klein, Melissa [Klein.Melissa@epa.gov]

Attachments: OGWDW Bi-Weekly_111419.docx

Location: 3233 WJCE

Start: 11/14/2019 4:00:00 PM **End**: 11/14/2019 4:30:00 PM

Show Time As: Busy

Sent: 8/5/2019 2:07:03 PM

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; McLain, Jennifer L.

[McLain.Jennifer@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; Tiago, Joseph

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John [Fuld.John@epa.gov]

CC: Macara Lousberg [Lousberg.Macara@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Risley, David

[Risley.David@epa.gov]; Gordon, Brittney [Gordon.Brittney@epa.gov]; Klein, Melissa [Klein.Melissa@epa.gov]

Subject: Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP)

Attachments: Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) ; Untitled Attachment; Untitled

Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) Intitled Attachment; Untitled Attachment; To be

rescheduled - Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP)

Location: 3233 WJCE

Start: 2/13/2019 9:00:00 PM **End**: 2/13/2019 9:45:00 PM

Show Time As: Busy

Recurrence: Weekly

Occurs on Wednesday every other week from 4:00 PM to 4:45 PM effective 2/13/2019.

Fuld, John [Fuld.John@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Thompkins, Anita [Thompkins.Anita@epa.gov]; Travers, David [Travers.David@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Tovar, Katlyn [tovar.katlyn@epa.gov]; Dennis, Allison [Dennis.Allison@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; McLain, Jennifer L. [McLain.Jennifer@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Dennis, Allison [Dennis.Allison@epa.gov]; Tovar, Katlyn [tovar.katlyn@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Travers, David [Travers.David@epa.gov]; Thompkins, Anita [Thompkins.Anita@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Fuld, John [Fuld.John@epa.gov]; Campbell, Ann [Campbell.Ann@epa.gov] Macara Lousberg [Lousberg.Macara@epa.gov]; Klein, Melissa [Klein.Melissa@epa.gov]; Gordon, Brittney [Gordon.Brittney@epa.gov]; Risley, David [Risley.David@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov];

CC:

[Gordon.Brittney@epa.gov]; Risley, David [Risley.David@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov] Lousberg, Macara [Lousberg.Macara@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Risley, David [Risley.David@epa.gov]; Gordon, Brittney [Gordon.Brittney@epa.gov]; Klein, Melissa [Klein.Melissa@epa.gov]

Subject: Brownbag -Bi-Weekly w/OGWDW Call it Ex. 6 Personal Privacy (PP)

Attachments: OGWDW Bi-Weekly_03112020_v1.docx

Location: 3233 WJCE

Start: 3/11/2020 4:15:00 PM End: 3/11/2020 5:00:00 PM

Show Time As: Tentative

Recurrence: (none)

Sent: 8/5/2019 2:07:03 PM

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; McLain, Jennifer L.

[Mclain.Jennifer@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; Tiago, Joseph

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Ross, David P [ross.davidp@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Dennis, Allison

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John [Fuld.John@epa.gov]

CC: Macara Lousberg [Lousberg.Macara@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Risley, David

[Risley.David@epa.gov]; Gordon, Brittney [Gordon.Brittney@epa.gov]; Klein, Melissa [Klein.Melissa@epa.gov]

Subject: Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP)

Attachments: Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) ; Untitled Attachment; Untitled

Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Bi-Weekly w/OGWDW Call in 2 Ex. 6 Personal Privacy (PP)

Ex. 6 Personal Privacy (PP): ; Untitled Attachment

Location: 3233 WJCE

Start: 2/13/2019 9:00:00 PM **End**: 2/13/2019 9:45:00 PM

Show Time As: Busy

Recurrence: Weekly

Occurs on Wednesday every other week from 4:00 PM to 4:45 PM effective 2/13/2019.

OGWDW Bi-Weekly with OW

March 11, 2020

Agenda

- COVID-19
- Perchlorate
- LCRR
- Lead Free
- PFAS
- EPA's Office of Children's Health Protection Upcoming Activities
- Water Security
 - March 4th Executive Engagement Forum Cross Sector Control Systems Interagency Working Group
- Heads Up
 - Quarterly Meeting w/Tracy Mehan and others

OGWDW Actions in OW-IO for Input

- Perchlorate
 - o Steps Water Systems Can Take to Address Perchlorate in Drinking Water
 - Reductions of Perchlorate in Drinking Water
 - Paper Based Briefing
- America's Workforce Initiative FRN
- Water Operator Hiring Guide
- Allotments of FY2020 Appropriations for the Voluntary Lead Testing in School and Child Care Program
 Drinking Water Grants, Authorized under Section 2107 of the Water Infrastructure Improvements for
 the Nation Act
- SDWIS Modernization Board Announcement for sharing with ECOS & ASDWA communities
- Challenges in Expediting Promulgation of Final Lead and Copper Rule Revisions

Upcoming External Engagements/Document Release Info/Events

- 3/10 Report. Issue to USAID the OITA cleared, "Trip Report from Preliminary Assessment of Las Pavas Water Treatment Plant and Distribution System."
- 3/10 Staff presentation. PFAS and the Safe Drinking Water Act to the American Water Resources
 Association (AWRA) National Capital Regional Section (NCRS) at Howard University

3/12	Webinar Recording. Implementation of Capacity Development Program – Related Safe
	Drinking Water Act Amendments in the America's Water Infrastructure Act
3/12	Webinar Recording. WIIN Grant: Reduction in Lead Exposure Via Drinking Water Request for Applications

Sent: 8/5/2019 2:07:03 PM

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; McLain, Jennifer L.

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[Risley.David@epa.gov]; Gordon, Brittney [Gordon.Brittney@epa.gov]; Klein, Melissa [Klein.Melissa@epa.gov]

Subject: Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP)

Attachments: Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) Untitled Attachment; Untitled

Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP)

Ex. 8 Personal Privacy (PP) Untitled Attachment; Untitled Attachment

Location: 3233 WJCE

Start: 2/13/2019 9:00:00 PM **End**: 2/13/2019 9:45:00 PM

Show Time As: Busy

Recurrence: Weekly

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To: Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov];

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[Bertrand.Charlotte@epa.gov]; Campbell, Ann [Campbell.Ann@epa.gov]

CC: Macara Lousberg [Lousberg.Macara@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Risley, David

[Risley.David@epa.gov]; Gordon, Brittney [Gordon.Brittney@epa.gov]; Klein, Melissa [Klein.Melissa@epa.gov];

Lousberg, Macara [Lousberg.Macara@epa.gov]

Subject: Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP)

Attachments: OGWDW Bi-Weekly_02112020.docx

Start: 2/12/2020 3:00:00 PM **End**: 2/12/2020 3:30:00 PM

Show Time As: Busy

Recurrence: (none)

OGWDW Bi-Weekly with OW

February 11, 2020

Agenda

- Lead Free
- Reg Det
- PFAS
- Workforce
- Perchlorate
- Technical Assistance Grant
- GAO/OIG Process

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; Mclain, Jennifer

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CC: Macara Lousberg [Lousberg.Macara@epa.gov]; Lousberg, Macara [Lousberg.Macara@epa.gov]; Guilaran, Yu-Ting

[Guilaran.Yu-Ting@epa.gov]; Risley, David [Risley.David@epa.gov]; Gordon, Brittney [Gordon.Brittney@epa.gov];

Klein, Melissa [Klein.Melissa@epa.gov]

Attachments: OGWDW Bi-Weekly_121019.docx

Location: 3233 WJCE

Start: 12/10/2019 2:30:00 PM **End**: 12/10/2019 3:00:00 PM

Show Time As: Tentative

Recurrence: (none)

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

 $Anna\ [wildeman.anna@epa.gov];\ Newberry,\ Debbie\ [Newberry.Debbie@epa.gov];\ Mclain,\ Jennifer$

[Mclain.Jennifer@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; Tiago, Joseph

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John [Fuld.John@epa.gov]; Campbell, Ann [Campbell.Ann@epa.gov]

Brownbag -Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP)

CC: Macara Lousberg [Lousberg.Macara@epa.gov]; Lousberg, Macara [Lousberg.Macara@epa.gov]; Guilaran, Yu-Ting

[Guilaran.Yu-Ting@epa.gov]; Risley, David [Risley.David@epa.gov]; Gordon, Brittney [Gordon.Brittney@epa.gov];

Klein, Melissa [Klein.Melissa@epa.gov]

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Attachments: OGWDW Bi-Weekly_03112020.docx

Location: 3233 WJCE

Start: 3/11/2020 4:00:00 PM **End**: 3/11/2020 4:45:00 PM

Show Time As: Busy

Subject:

Recurrence: (none)

OGWDW Bi-Weekly with OW

March 11, 2020

Agenda

COVID-19 Perchlorate Ex. 5 Deliberative Process (DP) LCRR Lead Free **PFAS** EPA's Office of Children's Health Protection Upcoming Activities Ex. 5 Deliberative Process (DP) Water Security March 4th Executive Engagement Forum - Cross Sector Control Systems Interagency Working Group Heads Up Quarterly Meeting w/Tracy Mehan and others **OGWDW Actions in OW-IO for Input** Perchlorate o Steps Water Systems Can Take to Address Perchlorate in Drinking Water o Reductions of Perchlorate in Drinking Water Paper Based Briefing America's Workforce Initiative FRN Water Operator Hiring Guide Allotments of FY2020 Appropriations for the Voluntary Lead Testing in School and Child Care Program Drinking Water Grants, Authorized under Section 2107 of the Water Infrastructure Improvements for the Nation Act Ex. 5 Deliberative Process (DP) SDWIS Modernization Board – Announcement for sharing with ECOS & ASDWA communities Challenges in Expediting Promulgation of Final Lead and Copper Rule Revisions Upcoming External Engagements/Document Release Info/Events Report. Issue to USAID the OITA cleared, "Trip Report from Preliminary Assessment of Las 3/10 Pavas Water Treatment Plant and Distribution System." 3/10 Staff presentation. PFAS and the Safe Drinking Water Act to the American Water Resources Association (AWRA) National Capital Regional Section (NCRS) at Howard University

3/12	Webinar Recording. Implementation of Capacity Development Program – Related Safe Drinking Water Act Amendments in the America's Water Infrastructure Act
3/12	Webinar Recording. WIIN Grant: Reduction in Lead Exposure Via Drinking Water Request f Applications

Fuld, John [Fuld.John@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Thompkins, Anita [Thompkins.Anita@epa.gov]; Travers, David [Travers.David@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Tovar, Katlyn [tovar.katlyn@epa.gov]; Dennis, Allison [Dennis.Allison@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; McLain, Jennifer L. [Mclain.Jennifer@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; McLain, Jennifer L. [Mclain.Jennifer@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Dennis, Allison [Dennis.Allison@epa.gov]; Tovar, Katlyn [tovar.katlyn@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Travers, David [Travers.David@epa.gov]; Thompkins, Anita [Thompkins.Anita@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Fuld, John [Fuld.John@epa.gov]; Campbell, Ann [Campbell.Ann@epa.gov] Macara Lousberg [Lousberg.Macara@epa.gov]; Klein, Melissa [Klein.Melissa@epa.gov]; Gordon, Brittney

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Subject: Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP)

Attachments: OGWDW Bi-Weekly_02112020_v1.docx

Start: 2/12/2020 3:00:00 PM **End**: 2/12/2020 3:30:00 PM

Show Time As: Busy

Recurrence: (none)

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; Mclain, Jennifer

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Klein, Melissa [Klein.Melissa@epa.gov]

Attachments: OGWDW Bi-Weekly_111419.docx

Location: 3233 WJCE

Start: 11/14/2019 4:00:00 PM **End**: 11/14/2019 4:30:00 PM

Show Time As: Busy

Recurrence: (none)

Fuld, John [Fuld.John@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Thompkins, Anita [Thompkins.Anita@epa.gov]; Travers, David [Travers.David@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Tovar, Katlyn [tovar.katlyn@epa.gov]; Dennis, Allison [Dennis.Allison@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; McLain, Jennifer L. [Mclain.Jennifer@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; McLain, Jennifer L. [Mclain.Jennifer@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Dennis, Allison [Dennis.Allison@epa.gov]; Tovar, Katlyn [tovar.katlyn@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Travers, David [Travers.David@epa.gov]; Thompkins, Anita [Thompkins.Anita@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Fuld, John [Fuld.John@epa.gov]; Campbell, Ann [Campbell.Ann@epa.gov] Macara Lousberg [Lousberg.Macara@epa.gov]; Klein, Melissa [Klein.Melissa@epa.gov]; Gordon, Brittney

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Attachments: OGWDW Bi-Weekly_02112020.docx

Start: 2/12/2020 3:00:00 PM **End**: 2/12/2020 3:30:00 PM

Show Time As: Busy

Recurrence: (none)

Sent: 8/5/2019 2:07:03 PM

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

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Attachments: Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP); Untitled Attachment; Untitled

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[8.8 Personal Privacy 877] Untitled Attachment; Untitled Attachment; Untitled Attachment

Location: 3233 WJCE

Start: 2/13/2019 9:00:00 PM **End**: 2/13/2019 9:45:00 PM

Show Time As: Busy

Recurrence: Weekly

Occurs on Wednesday every other week from 4:00 PM to 4:45 PM effective 2/13/2019.

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Attachments: OGWDW Bi-Weekly_01302020_v1.docx

Start: 1/30/2020 3:15:00 PM **End**: 1/30/2020 4:00:00 PM

Show Time As: Tentative

Recurrence: (none)

Sent: 8/5/2019 2:07:03 PM

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

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EX. 6 Parsonal Privacy (PP) Untitled Attachment; Untitled Attachment; Untitled Attachment

Location: 3233 WJCE

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Recurrence: Weekly

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TO BE RESCHEDULED Bi-Weekly w/OGWDW Call in **Ex. 6 Personal Privacy (PP)**

Attachments: OGWDW Bi-Weekly_02112020.docx

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Show Time As: Tentative

Recurrence: (none)

every 2 week(s) on Wednesday from 4:00 PM to 4:45 PM

TO BE RESCHEDULED

To: Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov];

Newberry, Debbie [Newberry.Debbie@epa.gov]; McLain, Jennifer L. [Mclain.Jennifer@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Aguirre, Janita

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[Risley.David@epa.gov]; Gordon, Brittney [Gordon.Brittney@epa.gov]; Klein, Melissa [Klein.Melissa@epa.gov];

Lousberg, Macara [Lousberg.Macara@epa.gov]

Attachments: OGWDW Bi-Weekly_01302020.docx

Start: 1/30/2020 2:45:00 PM **End**: 1/30/2020 3:30:00 PM

Show Time As: Busy

Recurrence: (none)

OGWDW Bi-Weekly with OW January 30, 2020

Agenda

- Lead Free
- Reg Det
- PFAS
- Workforce
- Perchlorate
- USDA MOA Option Selection
- PG&E Speaker for March 3 and March 4 EPA Water Sector PSPS Exercises
- Heads up
 - O PWSS Implementation Memo

CC:

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; Mclain, Jennifer

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[Guilaran.Yu-Ting@epa.gov]; Risley, David [Risley.David@epa.gov]

Attachments: OGWDW Biweekly_091319.docx; Perchlorate Comment Summary V4.pdf; Copy of LCR Revisions Proposal Schedule

9-12-19.pdf

Location: 3233 WJCE

Start: 9/13/2019 3:00:00 PM **End**: 9/13/2019 3:45:00 PM

Show Time As: Busy

Recurrence: (none)

Fuld, John [Fuld.John@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Thompkins, Anita [Thompkins.Anita@epa.gov]; Travers, David [Travers.David@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Tovar, Katlyn [tovar.katlyn@epa.gov]; Dennis, Allison [Dennis.Allison@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; McLain, Jennifer L. [Mclain.Jennifer@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Dennis, Allison [Dennis.Allison@epa.gov]; Tovar, Katlyn [tovar.katlyn@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Travers, David [Travers.David@epa.gov]; Thompkins, Anita [Thompkins.Anita@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Fuld, John [Fuld.John@epa.gov]; Campbell, Ann [Campbell.Ann@epa.gov] Macara Lousberg [Lousberg.Macara@epa.gov]; Klein, Melissa [Klein.Melissa@epa.gov]; Gordon, Brittney

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Attachments: OGWDW Bi-Weekly_01302020.docx

Start: 1/30/2020 2:45:00 PM **End**: 1/30/2020 3:30:00 PM

Show Time As: Tentative

Recurrence: (none)

OGWDW Bi-Weekly with OW January 30, 2020

Agenda

- Lead Free
- Reg Det
- PFAS
- Workforce
- Perchlorate

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Klein, Melissa [Klein.Melissa@epa.gov]

Attachments: OGWDW Bi-Weekly_103119.docx

Location: 3233 WJCE

Start: 10/31/2019 2:30:00 PM **End**: 10/31/2019 3:00:00 PM

Show Time As: Busy

Recurrence: (none)

Fuld, John [Fuld.John@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Thompkins, Anita [Thompkins.Anita@epa.gov]; Travers, David [Travers.David@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Tovar, Katlyn [tovar.katlyn@epa.gov]; Dennis, Allison [Dennis.Allison@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; McLain, Jennifer L. [Mclain.Jennifer@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; McLain, Jennifer L. [Mclain.Jennifer@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Dennis, Allison [Dennis.Allison@epa.gov]; Tovar, Katlyn [tovar.katlyn@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Travers, David [Travers.David@epa.gov]; Thompkins, Anita [Thompkins.Anita@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Fuld, John [Fuld.John@epa.gov]; Campbell, Ann [Campbell.Ann@epa.gov] Macara Lousberg [Lousberg.Macara@epa.gov]; Klein, Melissa [Klein.Melissa@epa.gov]; Gordon, Brittney

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Subject: Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP)

Attachments: OGWDW Bi-Weekly_02112020_v1.docx

Start: 2/12/2020 3:00:00 PM **End**: 2/12/2020 3:30:00 PM

Show Time As: Busy

Recurrence: (none)

Sent: 8/5/2019 2:07:03 PM

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; Tiago, Joseph

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CC: Macara Lousberg [Lousberg.Macara@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Risley, David

[Risley.David@epa.gov]; Gordon, Brittney [Gordon.Brittney@epa.gov]; Klein, Melissa [Klein.Melissa@epa.gov]

Subject: Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP)

Attachments: Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) Untitled Attachment; Untitled

Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled

Attachment; Untitled Attachment; Untitled Attachment

Location: 3233 WJCE

Start: 2/13/2019 9:00:00 PM **End**: 2/13/2019 9:45:00 PM

Show Time As: Busy

Recurrence: Weekly

Occurs on Wednesday every other week from 4:00 PM to 4:45 PM effective 2/13/2019.

Sent: 8/5/2019 2:07:03 PM

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; Mclain, Jennifer [Mclain.Jennifer@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; Tiago, Joseph

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Subject: Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP)

Attachments: Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) ; Untitled Attachment; Untitled

Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled

Attachment; Untitled Attachment

Location: 3233 WJCE

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[Guilaran.Yu-Ting@epa.gov]; Risley, David [Risley.David@epa.gov]

Attachments: OGWDW Biweekly_091319.docx; Perchlorate Comment Summary V4.pdf; Copy of LCR Revisions Proposal Schedule

9-12-19.pdf

Location: 3233 WJCE

Start: 9/13/2019 3:00:00 PM **End**: 9/13/2019 3:45:00 PM

Show Time As: Busy

Recurrence: (none)

Sent: 8/5/2019 2:07:03 PM

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CC: Lousberg, Macara [Lousberg.Macara@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Risley, David

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Subject: Bi-Weekly w/OGWDW

Attachments: Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP); Untitled Attachment; Untitled

Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Brownbag -Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP); Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Untitled Attachment; Bi-Weekly w/OGWDW; Untitled Attachment; Untitled Attachment; Canceled: Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) Untitled Attachment; Bi-Weekly

w/OGWDW; Untitled Attachment

Location: Call in Ex. 6 Personal Privacy (PP)

Start: 8/6/2020 8:00:00 PM **End**: 8/6/2020 8:45:00 PM

Show Time As: Busy

Recurrence: Weekly

Sent: 8/5/2019 2:07:03 PM

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Subject: Bi-Weekly w/OGWDW

Attachments: Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) 32; Untitled Attachment; Untitled

Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Brownbag -Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) Bi-Weekly w/OGWDW Call in Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) ; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Untitled Attachment; Bi-Weekly w/OGWDW; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Bi-Weekly w/OGWDW; Untitled Attac

w/OGWDW

Location: Call in Ex. 6 Personal Privacy (PP)

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[Tiago.Joseph@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Mejias,

Melissa [mejias.melissa@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; Bergman, Ronald

[Bergman.Ronald@epa.gov]; Travers, David [Travers.David@epa.gov]; Thompkins, Anita

[Thompkins.Anita@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Fuld, John [Fuld.John@epa.gov]; Campbell, Ann [Campbell.Ann@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]

CC: Lousberg, Macara [Lousberg.Macara@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Risley, David

[Risley.David@epa.gov]

Subject: Bi-Weekly w/OGWDW

Attachments: Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) Untitled Attachment; Untitled

Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Brownbag -Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) Intitled Attachment; Untitled Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) Intitled Attachment; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Untitled Attachment; Untitled

Weekly w/OGWDW; Untitled Attachment; Untitled Attachment; Bi-Weekly w/OGWDW; Untitled Attachment; Untitled Attachm

Cii

Canceled: Bi-Weekly w/OGWDW Call in **Ex. 6 Personal Privacy (PP)**; Untitled Attachment

Location: Call in Ex. 6 Personal Privacy (PP)

Start: 8/6/2020 8:00:00 PM **End**: 8/6/2020 8:45:00 PM

Show Time As: Tentative

Recurrence: Weekly

CC:

From: Owscheduling [Owscheduling@epa.gov]

Sent: 8/5/2019 2:07:03 PM

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; McLain, Jennifer L.

[McLain.Jennifer@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; Tiago, Joseph

[Tiago.Joseph@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Mejias,

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[Bergman.Ronald@epa.gov]; Travers, David [Travers.David@epa.gov]; Thompkins, Anita

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Lousberg, Macara [Lousberg.Macara@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Risley, David

[Risley.David@epa.gov]

Subject: Bi-Weekly w/OGWDW

Attachments: Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) Untitled Attachment; Untitled

Attachment; Untitled Attachment; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Untitled Attachment; Unt

Weekly w/OGWDW; Untitled Attachment; Untitled Attachment; Bi-Weekly w/OGWDW; Untitled Attachment; Untitled Attachment; Bi-Weekly w/OGWDW; Untitled Attachment; Untitled Attachmen

Canceled: Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP)

Location: Call in Ex. 6 Personal Privacy (PP)

Start: 8/19/2020 3:00:00 PM **End**: 8/19/2020 3:45:00 PM

Show Time As: Tentative

Recurrence: Weekly

Fuld, John [Fuld.John@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Thompkins, Anita [Thompkins.Anita@epa.gov]; Travers, David [Travers.David@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Tovar, Katlyn [tovar.katlyn@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Fuld, John [Fuld.John@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Thompkins, Anita [Thompkins.Anita@epa.gov]; Travers, David [Travers.David@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Tovar, Katlyn [tovar.katlyn@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; McLain, Jennifer L. [Mclain.Jennifer@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Owscheduling [Owscheduling@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; McLain, Jennifer L. [Mclain.Jennifer@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]

CC:

Klein, Melissa [Klein.Melissa@epa.gov]; Gordon, Brittney [Gordon.Brittney@epa.gov]; Klein, Melissa [Klein.Melissa@epa.gov]; Gordon, Brittney [Gordon.Brittney@epa.gov]; Risley, David [Risley.David@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Lousberg, Macara [Lousberg.Macara@epa.gov]; Risley, David [Risley.David@epa.gov]; Lousberg, Macara [Lousberg.Macara@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Braschayko, Kelley [braschayko.kelley@epa.gov]

Subject: Bi-Weekly w/OGWDW

Attachments: OGWDW Bi-Weekly Agenda with OW Sr. Leadership_06092020.docx

Location: Call in Ex. 6 Personal Privacy (PP)

Start: 6/9/2020 3:30:00 PM End: 6/9/2020 4:00:00 PM

Show Time As: Busy

Recurrence: (none)

every 2 week(s) on Wednesday from 4:00 PM to 4:45 PM

Attendee list adjusted to be OGWDW OD, DOD, and Special Assistant only.

8/5/2019 2:07:03 PM Sent:

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; McLain, Jennifer L.

[Mclain.Jennifer@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; Tiago, Joseph

[Tiago.Joseph@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Mejias,

Melissa [mejias.melissa@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; Bergman, Ronald

[Bergman.Ronald@epa.gov]; Travers, David [Travers.David@epa.gov]; Thompkins, Anita

[Thompkins.Anita@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Fuld,

John [Fuld.John@epa.gov]

CC: Lousberg, Macara [Lousberg.Macara@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Risley, David

[Risley.David@epa.gov]

Bi-Weekly w/OGWDW Subject:

Attachments: Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP); Untitled Attachment; Untitled

Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Brownbag.-Bi-Weeklv.w/QGWDW Call if Ex. 6 Personal Privacy (PP) ; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) Untitled Attachment; Bi-Weekly w/OGWDW Call in 2 Ex. 6 Personal Privacy (PP) Canceled: Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) ; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Untitled Attachment; Untitled Attachment; Bi-Weekly w/OGWDW; Untitled Attachment;

Untitled Attachment; Untitled Attachment; Bi-Weekly w/OGWDW; Untitled Attachment; Untitled Attachment;

Canceled: Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) ; Untitled Attachment

Call in Ex. 6 Personal Privacy (PP) Location:

Start: 8/6/2020 8:00:00 PM End: 8/6/2020 8:45:00 PM

Show Time As: Busy

Recurrence: Weekly

Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Dennis, Allison [Dennis.Allison@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Travers, David [Travers.David@epa.gov]; Thompkins, Anita [Thompkins.Anita@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Fuld, John [Fuld.John@epa.gov]; Fuld, John [Fuld.John@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Thompkins, Anita [Thompkins.Anita@epa.gov]; Travers, David [Travers.David@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Tovar, Katlyn [tovar.katlyn@epa.gov]; Dennis, Allison [Dennis.Allison@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; McLain, Jennifer L. [Mclain.Jennifer@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Owscheduling [Owscheduling@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; McLain, Jennifer L. [Mclain.Jennifer@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Campbell, Ann [Campbell.Ann@epa.gov]

CC:

Lousberg, Macara [Lousberg.Macara@epa.gov]; Risley, David [Risley.David@epa.gov]; Gordon, Brittney [Gordon.Brittney@epa.gov]; Klein, Melissa [Klein.Melissa@epa.gov]; Klein, Melissa [Klein.Melissa@epa.gov]; Gordon, Brittney [Gordon.Brittney@epa.gov]; Risley, David [Risley.David@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Lousberg, Macara [Lousberg.Macara@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Tovar, Katlyn [tovar.katlyn@epa.gov]; Braschayko, Kelley [braschayko.kelley@epa.gov]

Subject: Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP)

Attachments: OGWDW Biweekly_Agenda_04142020_v1.docx

Location: 2029910477, 1300632#

Start: 4/14/2020 8:00:00 PM **End**: 4/14/2020 8:30:00 PM

Show Time As: Busy

Recurrence: (none)

every 2 week(s) on Wednesday from 4:00 PM to 4:45 PM

Attendee list adjusted to be OGWDW OD, DOD, and Special Assistant only.

8/5/2019 2:07:03 PM Sent:

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; McLain, Jennifer L.

[Mclain.Jennifer@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; Tiago, Joseph

[Tiago.Joseph@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Mejias,

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[Bergman.Ronald@epa.gov]; Travers, David [Travers.David@epa.gov]; Thompkins, Anita

[Thompkins.Anita@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Fuld,

John [Fuld.John@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]

CC: Lousberg, Macara [Lousberg.Macara@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Risley, David

[Risley.David@epa.gov]

Bi-Weekly w/OGWDW Subject:

Attachments: Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) Untitled Attachment; Untitled

Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Brownbag -Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) 2; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) Canceled: Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) ; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) ; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Untitled Attachment; Untitled Attachment; Bi-Weekly w/OGWDW; Untitled Attachment;

Untitled Attachment; Untitled Attachment; Bi-Weekly w/OGWDW; Untitled Attachment; Untitled Attachment;

Canceled: Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) ; Untitled Attachment; Untitled Attachment

Call in Ex. 6 Personal Privacy (PP) Location:

Start: 8/6/2020 8:00:00 PM End: 8/6/2020 8:45:00 PM

Show Time As: Busy

Recurrence: Weekly

Sent: 8/5/2019 2:07:03 PM

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; McLain, Jennifer L.

[Mclain.Jennifer@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; Tiago, Joseph

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John [Fuld.John@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]

CC: Lousberg, Macara [Lousberg.Macara@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Risley, David

[Risley.David@epa.gov]

Subject: Bi-Weekly w/OGWDW

Attachments: Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) Untitled Attachment; Untitled

Attachment; Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) ; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Untitled Attachment; Untitled Attac

Canceled: Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) Untitled Attachment

Location: Call in Ex. 6 Personal Privacy (PP)

Start: 8/6/2020 8:00:00 PM End: 8/6/2020 8:45:00 PM

Show Time As: Busy

Recurrence: Weekly

CC:

From: Owscheduling [Owscheduling@epa.gov]

8/5/2019 2:07:03 PM Sent:

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; McLain, Jennifer L.

[Mclain.Jennifer@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; Tiago, Joseph

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Melissa [mejias.melissa@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; Bergman, Ronald

[Bergman.Ronald@epa.gov]; Travers, David [Travers.David@epa.gov]; Thompkins, Anita

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Lousberg, Macara [Lousberg.Macara@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Risley, David

[Risley.David@epa.gov]

Bi-Weekly w/OGWDW Subject:

Attachments: Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) أntitled Attachment; Untitled لأ

Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment: Brownbag_Bi-Weekly_w/QGWDW Call in Ex. 6 Personal Privacy (PP) Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) ; Canceled: Bi-.Weekly.w/QGWDW Call in Ex. 6 Personal Privacy (PP) Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Untitled Attachment; Untitled Attachment; Bi-Weekly w/OGWDW; Untitled Attachment; Untitled Attachment; Untitled Attachment; Bi-Weekly w/OGWDW; Untitled Attachment; Untitled Attachment;

Canceled: Bi-Weekly w/OGWDW Call in **Ex. 6 Personal Privacy (PP)** Untitled Attachment; Untitled Attachment

Location: Call in Ex. 6 Personal Privacy (PP)

Start: 8/6/2020 8:00:00 PM End: 8/6/2020 8:45:00 PM

Show Time As: Busy

Recurrence: Weekly

Fuld, John [Fuld.John@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Thompkins, Anita [Thompkins.Anita@epa.gov]; Travers, David [Travers.David@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Tovar, Katlyn [tovar.katlyn@epa.gov]; Dennis, Allison [Dennis.Allison@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; McLain, Jennifer L. [Mclain.Jennifer@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; McLain, Jennifer L. [Mclain.Jennifer@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Dennis, Allison [Dennis.Allison@epa.gov]; Tovar, Katlyn [tovar.katlyn@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Travers, David [Travers.David@epa.gov]; Thompkins, Anita [Thompkins.Anita@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Fuld, John [Fuld.John@epa.gov]; Campbell, Ann [Campbell.Ann@epa.gov] Macara Lousberg [Lousberg.Macara@epa.gov]; Klein, Melissa [Klein.Melissa@epa.gov]; Gordon, Brittney [Gordon.Brittney@epa.gov]; Risley, David [Risley.David@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov];

CC:

[Gordon.Brittney@epa.gov]; Risley, David [Risley.David@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov] Lousberg, Macara [Lousberg.Macara@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Risley, David [Risley.David@epa.gov]; Gordon, Brittney [Gordon.Brittney@epa.gov]; Klein, Melissa [Klein.Melissa@epa.gov]

Subject: Brownbag -Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP)

Attachments: OGWDW Bi-Weekly_03112020_v1.docx

Location: 3233 WJCE

Start: 3/11/2020 4:15:00 PM End: 3/11/2020 5:00:00 PM

Show Time As: Busy

Recurrence: (none)

Sent: 8/5/2019 2:07:03 PM

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; McLain, Jennifer L.

[McLain.Jennifer@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; Tiago, Joseph

[Tiago.Joseph@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Mejias,

Melissa [mejias.melissa@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; Bergman, Ronald

[Bergman.Ronald@epa.gov]; Travers, David [Travers.David@epa.gov]; Thompkins, Anita

[Thompkins.Anita@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Fuld,

John [Fuld.John@epa.gov]

CC: Lousberg, Macara [Lousberg.Macara@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Risley, David

[Risley.David@epa.gov]

Subject: Bi-Weekly w/OGWDW

Attachments: Untitled Attachment; Bi-Weekly w/OGWDW Call in 2 Ex. 6 Personal Privacy (PP) Untitled Attachment; Untitled

Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Brownbag -Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP); Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Bi-Weekly w/OGWDW; Untitled Attachment; Untitled Attachment; Bi-Weekly w/OGWDW; Untitled Attachment; Untitled Attachment; Bi-Weekly w/OGWDW; Untitled Attachment; Untitled

Weekly w/OGWDW; Untitled Attachment; Untitled Attachment; Bi-Weekly w/OGWDW; Untitled Attachment; Untitled Attachment; Bi-Weekly w/OGWDW; Untitled Attachment; Untitled Attachmen

Canceled: Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) Untitled Attachment

Location: Call in Ex. 6 Personal Privacy (PP)

Start: 8/19/2020 8:00:00 PM **End**: 8/19/2020 8:45:00 PM

Show Time As: Tentative

Recurrence: Weekly

CC:

From: Owscheduling [Owscheduling@epa.gov]

Sent: 8/5/2019 2:07:03 PM

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; McLain, Jennifer L.

[McLain.Jennifer@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; Tiago, Joseph

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Lousberg, Macara [Lousberg.Macara@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Risley, David

[Risley.David@epa.gov]

Subject: Bi-Weekly w/OGWDW

Attachments: Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) ; Untitled Attachment; Untitled

Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Brownbag -Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) | Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) | Si Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Untitled Attachment; Untitled

Untitled Attachment; Untitled Attachment; Bi-Weekly w/OGWDW; Untitled Attachment; Untitled Attachment;

Canceled: Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) Untitled Attachment

Location: Call in Ex. 6 Personal Privacy (PP)

Start: 8/19/2020 8:00:00 PM **End**: 8/19/2020 8:45:00 PM

Show Time As: Tentative

Recurrence: Weekly

8/5/2019 2:07:03 PM Sent:

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; McLain, Jennifer L.

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John [Fuld.John@epa.gov]

CC: Lousberg, Macara [Lousberg.Macara@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Risley, David

[Risley.David@epa.gov]

Bi-Weekly w/OGWDW Subject:

Attachments: Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) ; Untitled Attachment; Untitled

Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Brownbag -Bi-Weekly w/OGWDW Call in [Ex. 6 Personal Privacy (PP)] passcode (Ex. 8 Personal Privacy (PP)) Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) Canceled: Bi-Weekly w/OGWDW Call in _____ Ex. 6 Personal Privacy (PP) _____; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) ; Bi-Weekly w/OGWDW; Bi Weekly w/OGWDW; Untitled Attachment; Untitled Attachment; Bi-Weekly w/OGWDW; Untitled Attachment;

Untitled Attachment; Untitled Attachment; Bi-Weekly w/QGWDW: Untitled Attachment; Untitled Attachment;

Canceled: Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) ; Untitled Attachment

Call in Ex. 6 Personal Privacy (PP) Location:

Start: 8/19/2020 3:00:00 PM End: 8/19/2020 3:45:00 PM

Show Time As: Busy

Recurrence: Weekly

Sent: 8/5/2019 2:07:03 PM

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; McLain, Jennifer L.

[McLain.Jennifer@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; Tiago, Joseph

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John [Fuld.John@epa.gov]

CC: Lousberg, Macara [Lousberg.Macara@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Risley, David

[Risley.David@epa.gov]

Subject: Bi-Weekly w/OGWDW

Attachments: Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) ; Untitled Attachment; Untitled

Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Brownbag -Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP); Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP); Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) ; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Untitled Attachment; U

Untitled Attachment; Untitled Attachment; Bi-Weekly w/OGWDW; Untitled Attachment; Untitled At

Canceled: Bi-Weekly w/OGWDW Call ir Ex. 6 Personal Privacy (PP)

Location: Call in Ex. 6 Personal Privacy (PP)

Start: 8/19/2020 3:00:00 PM **End**: 8/19/2020 3:45:00 PM

Show Time As: Busy

Recurrence: Weekly

Sent: 8/5/2019 2:07:03 PM

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; McLain, Jennifer L.

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John [Fuld.John@epa.gov]

CC: Lousberg, Macara [Lousberg.Macara@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Risley, David

[Risley.David@epa.gov]

Subject: Bi-Weekly w/OGWDW

Attachments: Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP); Untitled Attachment; Untitled

Canceled: Bi-Weekly w/OGWDW Call in: Ex. 6 Personal Privacy (PP)

Location: Call in Ex. 6 Personal Privacy (PP)

Start: 7/29/2020 3:00:00 PM End: 7/29/2020 3:45:00 PM

Show Time As: Tentative

Recurrence: Weekly

Sent: 8/5/2019 2:07:03 PM

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; McLain, Jennifer L.

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John [Fuld.John@epa.gov]

CC: Lousberg, Macara [Lousberg.Macara@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Risley, David

[Risley.David@epa.gov]

Subject: Bi-Weekly w/OGWDW

Attachments: Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) 32; Untitled Attachment; Untitled

Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Brownbag -Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP)

Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP)

Untitled Attachment; Untitled Bi-Weekly W/OGWDW Call in Ex. 6 Personal Privacy (PP)

Bi-Weekly W/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Untitled Attachment; Untitled Attachment; Bi-Weekly w/OGWDW; Untitled Attachment;

Untitled Attachment; Untitled Attachment; Bi-Weekly w/OGWDW; Untitled Attachment; Untitled Attachment

Location: Call in Ex. 6 Personal Privacy (PP)

Start: 7/29/2020 3:00:00 PM **End**: 7/29/2020 3:45:00 PM

Show Time As: Tentative

Recurrence: Weekly

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; Mclain, Jennifer

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Campbell, Ann [Campbell.Ann@epa.gov]

CC: Macara Lousberg [Lousberg.Macara@epa.gov]; Lousberg, Macara [Lousberg.Macara@epa.gov]; Guilaran, Yu-Ting

[Guilaran.Yu-Ting@epa.gov]; Risley, David [Risley.David@epa.gov]; Gordon, Brittney [Gordon.Brittney@epa.gov];

Klein, Melissa [Klein.Melissa@epa.gov]

Attachments: OGWDW Bi-Weekly_103119.docx

Location: 3233 WJCE

Start: 10/31/2019 2:30:00 PM **End**: 10/31/2019 3:00:00 PM

Show Time As: Busy

Recurrence: (none)

Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Dennis, Allison [Dennis.Allison@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Travers, David [Travers.David@epa.gov]; Thompkins, Anita [Thompkins.Anita@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Fuld, John [Fuld.John@epa.gov]; Fuld, John [Fuld.John@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Thompkins, Anita [Thompkins.Anita@epa.gov]; Travers, David [Travers.David@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Tovar, Katlyn [tovar.katlyn@epa.gov]; Dennis, Allison [Dennis.Allison@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; McLain, Jennifer L. [Mclain.Jennifer@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Owscheduling [Owscheduling@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; McLain, Jennifer L. [Mclain.Jennifer@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Campbell, Ann [Campbell.Ann@epa.gov]

CC:

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Subject: Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP)

Attachments: OGWDW Biweekly_Agenda_04142020_v1.docx

Location: Ex. 6 Personal Privacy (PP)

Start: 4/14/2020 8:00:00 PM **End**: 4/14/2020 8:30:00 PM

Show Time As: Busy

Recurrence: (none)

every 2 week(s) on Wednesday from 4:00 PM to 4:45 PM

Attendee list adjusted to be OGWDW OD, DOD, and Special Assistant only.

Fuld, John [Fuld.John@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Thompkins, Anita [Thompkins.Anita@epa.gov]; Travers, David [Travers.David@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Tovar, Katlyn [tovar.katlyn@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Fuld, John [Fuld.John@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Thompkins, Anita [Thompkins.Anita@epa.gov]; Travers, David [Travers.David@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Tovar, Katlyn [tovar.katlyn@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; McLain, Jennifer L. [Mclain.Jennifer@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Owscheduling [Owscheduling@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; McLain, Jennifer L. [Mclain.Jennifer@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]

CC:

Klein, Melissa [Klein.Melissa@epa.gov]; Gordon, Brittney [Gordon.Brittney@epa.gov]; Klein, Melissa [Klein.Melissa@epa.gov]; Gordon, Brittney [Gordon.Brittney@epa.gov]; Risley, David [Risley.David@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Lousberg, Macara [Lousberg.Macara@epa.gov]; Risley, David [Risley.David@epa.gov]; Lousberg, Macara [Lousberg.Macara@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Braschayko, Kelley [braschayko.kelley@epa.gov]

Subject: Bi-Weekly w/OGWDW

Attachments: OGWDW Bi-Weekly Agenda with OW Sr. Leadership_06092020.docx

Location: (Ex. 6 Personal Privacy (PP)

Start: 6/9/2020 3:30:00 PM End: 6/9/2020 4:00:00 PM

Show Time As: Busy

Recurrence: (none)

every 2 week(s) on Wednesday from 4:00 PM to 4:45 PM

Attendee list adjusted to be OGWDW OD, DOD, and Special Assistant only.

Fuld, John [Fuld.John@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Thompkins, Anita [Thompkins.Anita@epa.gov]; Travers, David [Travers.David@epa.gov]; Bergman, Ronald [Bergman.Ronald@epa.gov]; Tovar, Katlyn [tovar.katlyn@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; McLain, Jennifer L. [Mclain.Jennifer@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Owscheduling [Owscheduling@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]; McLain, Jennifer L. [Mclain.Jennifer@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]

CC:

Klein, Melissa [Klein.Melissa@epa.gov]; Gordon, Brittney [Gordon.Brittney@epa.gov]; Risley, David

[Risley.David@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Lousberg, Macara

[Lousberg.Macara@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov];

Braschayko, Kelley [braschayko.kelley@epa.gov]; Tiago, Joseph [Tiago.Joseph@epa.gov]; Risley, David

[Risley.David@epa.gov]

Subject: Bi-Weekly w/OGWDW

Attachments: OGWDW Bi-Weekly Agenda with OW Sr. Leadership_05272020_FINAL.docx

Location: Call in Ex. 6 Personal Privacy (PP)

Start: 5/27/2020 3:30:00 PM **End**: 5/27/2020 4:00:00 PM

Show Time As: Busy

Recurrence: (none)

every 2 week(s) on Wednesday from 4:00 PM to 4:45 PM

Attendee list adjusted to be OGWDW OD, DOD, and Special Assistant only.

Sent: 8/5/2019 2:07:03 PM

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; McLain, Jennifer L.

[McLain.Jennifer@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; Tiago, Joseph

[Tiago.Joseph@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Mejias,

Melissa [mejias.melissa@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; Bergman, Ronald

[Bergman.Ronald@epa.gov]; Travers, David [Travers.David@epa.gov]; Thompkins, Anita

[Thompkins.Anita@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Fuld,

John [Fuld.John@epa.gov]

CC: Lousberg, Macara [Lousberg.Macara@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Risley, David

[Risley.David@epa.gov]

Subject: Bi-Weekly w/OGWDW

Attachments: Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) Untitled Attachment; Untitled

Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Brownbag -Bi-Weekly w/OGWDW Call in **Ex. 6 Personal Privacy (PP)**; Bi-Weekly w/OGWDW Call in **Ex. 6 Personal Privacy (PP)**; Untitled Attachment; Bi-Weekly w/OGWDW Call in **Ex. 6 Personal Privacy (PP)**; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Untitled Attachment; Bi-Weekly w/OGWDW Call in **Ex. 6 Personal Privacy (PP)**; Bi-Wee

Weekly w/OGWDW

Location: Call in Ex. 6 Personal Privacy (PP)

Start: 7/29/2020 3:00:00 PM End: 7/29/2020 3:45:00 PM

Show Time As: Tentative

Recurrence: Weekly

Forsgren, Lee [Forsgren.Lee@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Shimkin, Martha [Shimkin.Martha@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; McLain, Jennifer L. [Mclain.Jennifer@epa.gov]; Sawyers, Andrew [Sawyers.Andrew@epa.gov]; Nagle, Deborah [Nagle.Deborah@epa.gov]; Goodin, John [Goodin.John@epa.gov]; Lape, Jeff [lape.jeff@epa.gov]; Connors, Sandra [Connors.Sandra@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Vazquez, Sharon [Vazquez.Sharon@epa.gov]; Kitamura, Louise [Kitamura.Louise@epa.gov]; Frace, Sheila [Frace.Sheila@epa.gov]; Moore, Kristie [Moore.Kristie@epa.gov]; Gollan, Christopher [Gollan.Christopher@epa.gov]; Gentile, Laura [Gentile.Laura@epa.gov]; Green-Goldsborough, Kimberly [Green-Goldsborough.Kimberly@epa.gov]; Lieberman, Judy [Lieberman.Judy@epa.gov]; Maguire, Charles [maguire.charles@epa.gov]; Rush, Randall [Rush.Randall@epa.gov]; Varnado, Miriam [Varnado.Miriam@epa.gov] Bissonette, Eric [Bissonette.Eric@epa.gov]; Cummings, Travis [Cummings.Travis@epa.gov]; Stabenfeldt, Lynn

CC:

[maguire.charles@epa.gov]; Rush, Randall [Rush.Randall@epa.gov]; Varnado, Miriam [Varnado.Miriam@epa.gov] [Stabenfeldt.Lynn@epa.gov]; Farber, Kit [Farber.Kit@epa.gov]; Stebe, Katherine [Stebe.Katherine@epa.gov]; Clark, Jackie [Clark.Jackie@epa.gov]; Eddy, Elizabeth [Eddy.Elizabeth@epa.gov]; Bains, Susanna [Bains.Susanna@epa.gov]; Bankester, Lenny [Bankester.Lenny@epa.gov]; Ortiz, Agnes [Ortiz.Agnes@epa.gov]; Nelson, Tomeka [Nelson.Tomeka@epa.gov]; Highsmith, Damon [Highsmith.Damon@epa.gov]; Drummond, Laura [Drummond.Laura@epa.gov]; Giddings, Daniel [giddings.daniel@epa.gov]; King, RyanM [King.RyanM@epa.gov]; Kuntz, Kerry [Kuntz.Kerry@epa.gov]; Woods, Terry [Woods.Terry@epa.gov]; Lousberg, Macara [Lousberg.Macara@epa.gov]; Ruf, Christine [Ruf.Christine@epa.gov]; Evalenko, Sandy [Evalenko.Sandy@epa.gov]; Moore, Steven [Moore.Steven@epa.gov]; Torrez, Alfredo [Torrez.Alfredo@epa.gov]; Erickson, Amber [Erickson.Amber@epa.gov]; Stevens, Robert [Stevens.Robert@epa.gov]; WigginsLewis, Miriam [WigginsLewis.Miriam@epa.gov]; Zipf, Lynn [Zipf.Lynn@epa.gov]; Rey, Dominique [Rey.Dominique@epa.gov]; Martinez, Maria [Martinez.Maria@epa.gov]; Budd, Blair (Kathryn) [budd.kathryn@epa.gov]; Gutierrez, Sally [Gutierrez.Sally@epa.gov]; Lopez-Carbo, Maria [Lopez-Carbo.Maria@epa.gov]; Miller, Wynne [Miller.Wynne@epa.gov]; Dickens, Sandy [Dickens.Sandy@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Smith, Bernicel [Smith.Bernicel@epa.gov]; Mottley, Tanya [Mottley.Tanya@epa.gov]; Gude, Karen [Gude.Karen@epa.gov]; McMiller, Nettie [McMiller.Nettie@epa.gov]; Young, Dwane [Young.Dwane@epa.gov]; Wall, Tom [Wall.Tom@epa.gov]

Attachments: Strategic Review Files 3-20-20.pdf; March MBR Countermeasures.pdf; OW March Business Review Agenda and

Attachments.pdf

Start: 3/25/2020 1:00:00 PM **End**: 3/25/2020 4:00:00 PM

Show Time As: Busy

Recurrence: (none)

Sent: 8/5/2019 2:05:04 PM

To: Owscheduling [Owscheduling@epa.gov]; Nagle, Deborah [Nagle.Deborah@epa.gov]; Best-Wong, Benita [Best-

Wong.Benita@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; McLain, Jennifer L.

[Mclain.Jennifer@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; Sawyers, Andrew [Sawyers.Andrew@epa.gov]; Lousberg, Macara [Lousberg.Macara@epa.gov]; Goodin, John [Goodin.John@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Risley, David [Risley.David@epa.gov];

Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]

Subject: Weekly General w/ ODs

Attachments: Untitled Attachment; Untitled Attachme

Untitled Attachment; Untitled

Attachment

Location: 3233 WJCE Call in Ex. 6 Personal Privacy (PP)

Start: 2/20/2019 5:00:00 PM **End**: 2/20/2019 6:00:00 PM

Show Time As: Busy

Recurrence: Weekly

every Wednesday from 12:00 PM to 1:00 PM

Owscheduling [Owscheduling@epa.gov] From:

8/5/2019 2:07:03 PM Sent:

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; McLain, Jennifer L.

[Mclain.Jennifer@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; Tiago, Joseph

[Tiago.Joseph@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Mejias,

Melissa [mejias.melissa@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; Bergman, Ronald

[Bergman.Ronald@epa.gov]; Travers, David [Travers.David@epa.gov]; Thompkins, Anita

[Thompkins.Anita@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Fuld,

John [Fuld.John@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]

CC: Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Risley, David [Risley.David@epa.gov]

Subject: Bi-Weekly w/OGWDW

Attachments: Untitled Attachment; Bi-Weekly w/OGWDW Call in [Ex. 6 Personal Privacy (PP)]; Untitled Attachment; Untitled

Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Brownbag -Bi-Weekly w/OGWDW Call in [Ex.6 Personal Privacy (PP) ; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) Untitled Attachment; Untitled Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) ; Bi-Weekly w/OGWDW ; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Untitled Attachment; Untitled Attachment; Bi-Weekly w/OGWDW; Untitled Attachment; Untitled Attachment; Untitled Attachment; Bi-Weekly w/OGWDW; Untitled Attachment; Untitled Attachment;

Canceled: Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) Untitled Attachment; Bi-Weekly

w/OGWDW; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment

Location: Call in Ex. 6 Personal Privacy (PP)

Start: 9/8/2020 3:00:00 PM End: 9/8/2020 3:45:00 PM

Show Time As: Busy

Recurrence: Weekly

Sent: 8/5/2019 2:07:03 PM

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; McLain, Jennifer L.

[Mclain.Jennifer@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; Tiago, Joseph

[Tiago.Joseph@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Mejias,

Melissa [mejias.melissa@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; Bergman, Ronald

[Bergman.Ronald@epa.gov]; Travers, David [Travers.David@epa.gov]; Thompkins, Anita

[Thompkins.Anita@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Fuld,

John [Fuld.John@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]

CC: Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Risley, David [Risley.David@epa.gov]

Subject: Bi-Weekly w/OGWDW

Attachments: Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) ; Untitled Attachment; Untitled

w/OGWDW; Untitled Attachment; Untitled Attachment

Location: Call in 2 Ex. 6 Personal Privacy (PP)

Start: 9/8/2020 3:00:00 PM **End**: 9/8/2020 3:45:00 PM

Show Time As: Tentative

Recurrence: Weekly

every Tuesday from 11:00 AM to 11:45 AM

Sent: 8/5/2019 2:07:03 PM

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; McLain, Jennifer L.

[Mclain.Jennifer@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; Tiago, Joseph

[Tiago.Joseph@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Mejias,

Melissa [mejias.melissa@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; Bergman, Ronald

[Bergman.Ronald@epa.gov]; Travers, David [Travers.David@epa.gov]; Thompkins, Anita

[Thompkins.Anita@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Fuld,

John [Fuld.John@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]

CC: Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Risley, David [Risley.David@epa.gov]

Subject: Bi-Weekly w/OGWDW

Attachments: Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP); Untitled Attachment; Untitled

Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Brownbag -Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Untitled Attachment; Untit

Canceled: Bi-Weekly w/OGWDW Call in [Ex. 6 Personal Privacy (PP) Untitled Attachment; Bi-Weekly

w/OGWDW; Untitled Attachment; Untitled Attachment

Location: Call in 2 Ex. 6 Personal Privacy (PP)

Start: 9/8/2020 8:00:00 PM End: 9/8/2020 8:45:00 PM

Show Time As: Busy

Recurrence: Weekly

every Tuesday from 4:00 PM to 4:45 PM

Sent: 8/5/2019 2:07:03 PM

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; McLain, Jennifer L.

[Mclain.Jennifer@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; Tiago, Joseph

[Tiago.Joseph@epa.gov]; Mason, Paula [Mason.Paula@epa.gov]; Best-Wong, Benita [Best-Wong.Benita@epa.gov]; Wadlington, Christina [Wadlington.Christina@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Mejias,

Melissa [mejias.melissa@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; Bergman, Ronald

[Bergman.Ronald@epa.gov]; Travers, David [Travers.David@epa.gov]; Thompkins, Anita

[Thompkins.Anita@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Spraul, Greg [Spraul.Greg@epa.gov]; Fuld,

John [Fuld.John@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]

CC: Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Risley, David [Risley.David@epa.gov]

Subject: Bi-Weekly w/OGWDW

Attachments: Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP); Untitled Attachment; Untitled

w/OGWDW; Untitled Attachment; Untitled Attachment; Untitled Attachment

Location: Call in Ex. 6 Personal Privacy (PP)

Start: 9/8/2020 3:00:00 PM **End**: 9/8/2020 3:45:00 PM

Show Time As: Busy

Recurrence: Weekly

Sent: 8/5/2019 2:07:03 PM

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; McLain, Jennifer L.

[McLain.Jennifer@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; Tiago, Joseph

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John [Fuld.John@epa.gov]; Kramer, Jessica L. [kramer.jessical@epa.gov]

CC: Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Risley, David [Risley.David@epa.gov]

Subject: Bi-Weekly w/OGWDW

Attachments: Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) ; Untitled Attachment; Untitled

w/OGWDW; Untitled Attachment; Untitled Attachment

Location: Call in Ex. 6 Personal Privacy (PP)

Start: 9/10/2020 8:00:00 PM **End**: 9/10/2020 8:45:00 PM

Show Time As: Tentative

Recurrence: Weekly

every Thursday from 4:00 PM to 4:45 PM

Sent: 8/5/2019 2:07:03 PM

To: Owscheduling [Owscheduling@epa.gov]; Rodgers-Jenkins, Crystal [Rodgers-Jenkins.Crystal@epa.gov]; Wildeman,

Anna [wildeman.anna@epa.gov]; Newberry, Debbie [Newberry.Debbie@epa.gov]; McLain, Jennifer L.

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CC: Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Risley, David [Risley.David@epa.gov]

Subject: Bi-Weekly w/OGWDW

Attachments: Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP); Untitled Attachment; Untitled

Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Brownbag -Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP); Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP); Untitled Attachment; Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) ; Canceled: Bi-Weekly w/OGWDW Call in Ex. 6 Personal Privacy (PP) ; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Bi-Weekly w/OGWDW; Untitled Attachment; Untitled Attach

w/OGWDW; Untitled Attachment; Untitled Attachment

Location: Call in Ex. 6 Personal Privacy (PP)

Start: 8/6/2020 8:00:00 PM **End**: 8/6/2020 8:45:00 PM

Show Time As: Busy

Recurrence: Weekly

every Thursday from 4:00 PM to 4:45 PM

Sent: 8/5/2019 2:05:04 PM

To: Owscheduling [Owscheduling@epa.gov]; Nagle, Deborah [Nagle.Deborah@epa.gov]; Best-Wong, Benita [Best-

Wong.Benita@epa.gov]; Wildeman, Anna [wildeman.anna@epa.gov]; McLain, Jennifer L.

[McLain.Jennifer@epa.gov]; Penman, Crystal [Penman.Crystal@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; McDonough, Owen [mcdonough.owen@epa.gov]; Sawyers, Andrew [Sawyers.Andrew@epa.gov]; Lousberg, Macara [Lousberg.Macara@epa.gov]; Goodin, John [Goodin.John@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Risley, David [Risley.David@epa.gov];

Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]

Subject: Weekly General w/ ODs

Attachments: Untitled Attachment; Untitled Attachme

Untitled Attachment; Canceled: Brownbag: General w/ ODs; Untitled Attachment; Untitled Attachment; Canceled:

Weekly General w/ ODs; Untitled Attachment

Location: 3233 WJCE Call in Ex. 6 Personal Privacy (PP)

Start: 2/20/2019 5:00:00 PM **End**: 2/20/2019 6:00:00 PM

Show Time As: Busy

Recurrence: Weekly

every Wednesday from 12:00 PM to 1:00 PM

Appointment

From: Owscheduling [Owscheduling@epa.gov]

Sent: 1/6/2020 3:24:55 PM

To: Owscheduling [Owscheduling@epa.gov]; Ross, David P [ross.davidp@epa.gov]; Mclain, Jennifer

[Mclain.Jennifer@epa.gov]; Burneson, Eric [Burneson.Eric@epa.gov]; Forsgren, Lee [Forsgren.Lee@epa.gov]; Betts, Aaron [Betts.Aaron@epa.gov]; Nagle, Deborah [Nagle.Deborah@epa.gov]; Behl, Betsy [Behl.Betsy@epa.gov]; Wehling, Carrie [Wehling.Carrie@epa.gov]; Wendelowski, Karyn [wendelowski.karyn@epa.gov]; Bertrand, Charlotte

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CC: Tiago, Joseph [Tiago.Joseph@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Fotouhi, David

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[mutz.john@epa.gov]; Mejias, Melissa [mejias.melissa@epa.gov]; Tovar, Katlyn [tovar.katlyn@epa.gov]; Leopold,

Matt (OGC) [Leopold.Matt@epa.gov]

Subject: Perchlorate Option Selection

Attachments: Time Sensitive Meeting Request: Perchlorate Option Selection; Option Selection for Perchlorate 1-7-20 .docx

Location: 3219A WJCE

Start: 1/7/2020 4:00:00 PM **End**: 1/7/2020 5:00:00 PM

Show Time As: Busy

Message

From: Tiago, Joseph [Tiago.Joseph@epa.gov]

Sent: 11/8/2019 9:15:10 PM

To: Penman, Crystal [Penman.Crystal@epa.gov]; Aguirre, Janita [Aguirre.Janita@epa.gov]; Mejias, Melissa

[mejias.melissa@epa.gov]

Subject: Time Sensitive Meeting Request: Perchlorate Option Selection

Good afternoon Crystal, Janita, and Mel!

I'd like to request your assistance in scheduling two Perchlorate Option Selection meetings, one with Dave and the other with the Administrator.

EPA is under consent decree deadline of June 19, 2020 for a final decision on perchlorate. In order to meet that deadline, we will need to obtain a decision from the Administrator on the preferred option by November 29th 2019 to allow for timely agency review.

Under the current two proposed options, OW will need to either begin preparing Final Regulatory Determination Package (FRN, comment response document etc.) or prepare a final Rule package (FRN, EA, comment response document etc.) on November 29th 2019.

Please help with the following two meetings:

1- Meeting with Dave

- Subject: Perchlorate Option Selection
- Timing: NLT Friday November 15th
- Purpose: This will be a pre-brief for Option Selection meeting with the Administrator.
- **Driver**: Regulatory decision for Perchlorate should be obtained by November 30th to assure timely agency review and compliance with consent decree.
- **Preferred Date**: Thursday, November 14th in the afternoon if possible. We can move the Lead in Schools briefing for Charlotte to a different day the following week if needed. (Both Eric and Charlotte are in Cincinnati on Tuesday and Wednesday).
- Duration: 1 hour
- Participants: Jennifer McLain, Yu-Ting Guilaran, Eric Burneson, Macara Lousberg, Carrie Wehling, Karyn Wendelowski, Samuel Hernandez, Rajiv Khera, Lisa Christ, Deborah Nagle, Betsy Behl, Jamie Strong, Joe Tiago

2- Meeting with the Administrator

- a. Subject: Perchlorate Option Selection
- b. Timing: NLT Friday November 29th
- c. *Purpose*: This will be an Option Selection meeting with the Administrator.
- d. **Driver**: Regulatory decision for Perchlorate should be obtained by November 30th to assure timely agency review and compliance with consent decree.
- e. *Preferred Dates*: November 21, 22, 25, 26, or 27 if possible.
- f. Duration: 1 hour
- g. *Participants*: Principals from each office, Jennifer McLain, and Eric Burneson.

Thank you so much for your assistance!

Joe.

(202) 564-0340



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Thyroid antagonists and thyroid indicators in U.S. pregnant women in the Vanguard Study of the National Children's Study

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Abstract

The sodium iodide-symporter (NIS) mediates uptake of iodide into thyroid follicular cells. This key step in thyroid hormone synthesis is inhibited by perchlorate, thiocyanate (SCN) and nitrate (NO3) anions. When these exposures occur during pregnancy the resulting decreases in thyroid hormones may adversely affect neurodevelopment of the human fetus. Our objectives were to describe and examine the relationship of these anions to the serum thyroid indicators, thyroid stimulating hormone (TSH) and free thyroxine (FT4), in third trimester women from the initial Vanguard Study of the National Children's Study (NCS); and to compare urine perchlorate results with those in pregnant women from the National Health and Nutritional Examination Survey (NHANES).

Urinary perchlorate, SCN, NO3, and iodine, serum TSH, FT4, and cotinine were measured and a food frequency questionnaire (FFQ) was administered to pregnant women enrolled in the initial Vanguard Study. We used multiple regression models of FT4 and TSH that included perchlorate equivalent concentration (PEC, which estimates combined inhibitory effects of the anions perchlorate, SCN, and NO3 on the NIS). We used multiple regression to model predictors of each urinary anion, using FFQ results, drinking water source, season of year, smoking status, and demographic characteristics. Descriptive statistics were calculated for pregnant women in NHANES 2001–2012.

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Conflict of Interest: None of the authors has any actual or potential conflicts of interest to disclose.

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The geometric mean (GM) for urinary perchlorate was 4.04 μ g/L, for TSH 1.46 mIU/L, and the arithmetic mean for FT4 1.11 ng/dL in 359 NCS women. In 330 women with completed FFQs, consumption of leafy greens, winter season, and Hispanic ethnicity were significant predictors of higher urinary perchlorate, which differed significantly by study site and primary drinking water source, and bottled water was associated with higher urinary perchlorate compared to filtered tap water. Leafy greens consumption was associated with higher urinary NO3 and higher urinary SCN. There was no association between urinary perchlorate or PEC and TSH or FT4, even for women with urinary iodine < 100 μ g/L. GM urinary perchlorate concentrations in the full sample (n=494) of third trimester NCS women (4.03 μ g/L) were similar to pregnant women in NHANES (3.58 μ g/L).

Keywords

National Children's Study; Perchlorate; Biomonitoring; NHANES; Pregnancy

1.0 Introduction

The perchlorate anion is an oxidizing agent, and its ammonium salt has been used in rocket and missile propellant systems, fireworks, matches, and for several other industrial uses (Trumpolt et al, 2005). Perchlorate is formed in the atmosphere and can accumulate in the soils of arid regions (Dasgupta et al, 2005). Human exposure sources include contaminated drinking water and consumption of foods containing perchlorate; mainly, milk and high surface area plants such as leafy green vegetables (Murray et al, 2008; Sanchez et al, 2009). Human health concerns are related to the ability of perchlorate to competitively inhibit iodide uptake by the sodium-iodide symporter (NIS) of the thyroid gland (Dohan and Carrasco, 2003; Tonacchera et al, 2004). So effective is it for blocking iodide uptake that high dose potassium perchlorate (up to 1000 mg per day) historically was used to treat hyperthyroidism (Crooks and Wayne, 1960). Current concerns about potential anti-thyroid effects of environmental perchlorate exposure focus largely on pregnant women. During fetal development, adequate thyroid hormone is essential for neurological development, and until 20 weeks gestation, the fetus is dependent on maternal thyroid hormone (Pearce, 2012). At the same time, adequate maternal iodine intake is essential for thyroid hormone production. Iodine intake is considered to be adequate in a population of pregnant women with a urinary median iodine concentration of 150–249 µg/L (WHO, 2008). Perchlorate absorbed into the body easily passes through the placenta, and fetal exposure parallels maternal exposure (Blount et al 2009).

The U.S. Environmental Protection Agency (EPA) has begun to develop a drinking water standard for perchlorate (U.S. EPA, 2011), but the majority of the U.S. population exposure to perchlorate derives from dietary sources. Huber et al (2011) used National Health and Nutrition Examination Survey (NHANES) data and estimated that approximately 80% of urinary perchlorate was derived from dietary sources. Others also have shown diet as the primary perchlorate exposure source for U.S. residents, based on tap water perchlorate concentrations (Mendez et al, 2010), dietary analysis (Murray, et al 2008), and analysis of

tap water and exposure data from NHANES (Blount et al, 2010; Lau et al, 2013; Yang et al, 2012).

Perchlorate is widespread in the U.S. population, with virtually 100% of participants in the NHANES having detectable urinary concentrations (Blount et al, 2007; CDC, 2015). The ubiquitous exposure to perchlorate, in combination with decreasing iodine intake, especially in women of child-bearing ages (Caldwell et al, 2013), has given impetus to examine the relationship among thyroid function, perchlorate exposure, and urinary iodine. Results have been inconsistent. U.S. women with marginal iodine intake (urinary iodine $\leq 100 \,\mu g/L$) and higher urinary perchlorate had lower thyroxine and higher thyroid stimulating hormone (TSH) values compared to women with urinary iodine $\geq 100 \,\mu\text{g/L}$ (Blount et al, 2006). Prenatal perchlorate exposure increased the risk for elevated TSH in the newborn (Steinmaus et al, 2010) and was associated with lower IQ in childhood (Taylor et al, 2014). However, no association was found between urinary perchlorate and TSH or free thyroxine (FT4) in California women who had experienced perchlorate contamination of drinking water (Gold et al, 2013). Most studies in pregnant women have not found an association between measures of thyroid function (e.g. TSH, FT4, or thyroglobulin) and urinary perchlorate concentrations measured in the first or second trimesters, regardless of urinary iodine status (Pearce et al, 2010, 2011, and 2012; Tellez et al, 2005). However, others have found that urinary perchlorate was a significant predictor for increased TSH and decreased FT4 (Charatcharoenwitthaya et al, 2014; Steinmaus et al, 2015).

The anions thiocyanate (SCN) and nitrate (NO3) also inhibit the NIS and are virtually ubiquitous exposures because of their presence in green leafy vegetables and other foods (Clements 1960; Hord et al, 2009). Cruciferous vegetables, including cabbage, kale, broccoli, and cauliflower, are rich in SCN (Clements 1960). Cyanide in tobacco smoke also contributes significantly to urinary SCN in smokers (Buratti et al, 1997). Higher concentrations of these anions may act together: increased urine SCN (from smoking) and perchlorate interacted to reduce serum thyroxine in women with lower urine iodine concentrations ($< 100 \ \mu g/L$) (Steinmaus et al, 2013). The perchlorate equivalent concentration (PEC) has been proposed as a tool to estimate combined inhibitory effects of perchlorate, SCN, and NO3 on the NIS, (Bruce et al, 2013; Tonacchera et al, 2004) and to examine the combined effects of these anions on thyroid function. However, the PEC was weakly predictive of thyroxine and no other measures of thyroid function, and PEC was not predictive of thyroid indicators in women with inadequate iodine intake (Bruce et al, 2013).

Two sources of variability may contribute to the inconsistent results of studies that examined effects of perchlorate or PEC on thyroid hormones in pregnancy. First pertains to the physiologic changes in FT4 and TSH, particularly in early pregnancy (first-to-early second trimester). FT4 concentrations typically increase by as much as 50% in the first trimester, and TSH decreases because of increasing human chorionic gonadotropin (hCG) produced by the placenta (Stagnaro-Green et al, 2011). Second is that widely used immunologic assays for FT4 can be unreliable and subject to biases related to protein bound T4 and related proteins (Sapin et al, 2003). We sought to reduce these sources of variability by limiting our sample to third trimester women and by measuring serum FT4 in a method that uses equilibrium dialysis to separate free from protein-bound T4.

In this analysis, we evaluated perchlorate and a combined effect of the NIS inhibitors (as PEC) on FT4 and TSH, and also examined determinants of urinary perchlorate, SCN, and NO3 in third trimester women enrolled in the Vanguard Study of the NCS. We also present urinary perchlorate results from similar-aged pregnant women in NHANES 2001–2012 for comparison.

2. Methods

2.1. Study populations

The NCS Vanguard Study was a feasibility study to test the proposed recruitment, enrollment, and study visit assessment methodologies for a planned large-scale epidemiological cohort study of children and their parents. As described by Baker et al. (2014), 1399 women were enrolled in the NCS initial Vanguard Study from 2009—2010 from seven locations: Queens County, New York; Duplin County, North Carolina; Salt Lake County, Utah; Orange County, California; Montgomery County, Pennsylvania; Waukesha County, Wisconsin; and a composite location of four adjacent counties in South Dakota and Minnesota. During pregnancy, women had up to two visits that included an extensive interview, a physical examination, and collection of blood and urine specimens and environmental samples. This study reports a sample of third trimester pregnant women enrolled in the Vanguard Study and measurements made as part of a pilot study conducted with the Centers for Disease Control and Prevention (Mortensen and Hirschfeld, 2012).

NHANES has been conducted annually since 1999, releases data in two year cycles, and provides an ongoing assessment of the health, nutrition, health-related behaviors, and environmental chemical exposures in the U.S. population (CDC, 2013). Using a stratified, multistage, probability cluster design, NHANES obtains a representative sample of the non-institutionalized U.S. population. Additional information is available at: http://www.cdc.gov/nchs/nhanes/about_nhanes.htm. Each year, approximately 5000 residents randomly selected in 15 counties across the U.S. are asked to participate through an advance letter, providing information that the household has been selected as part of the NHANES sample. A field interviewer conducts screening and enrollment, and completes the household interview at the home. Subsequent interviews, physical examination, and biological specimen collections are conducted at the Mobile Examination Center (MEC). The average participation rate for data collected at the MEC is approximately 80% (NCHS, 2013). Informed consent was obtained from all NHANES participants prior to collecting, data or specimens, and the analysis presented here used only de-identified data that were publicly available.

We used NHANES 2001–2012 urine perchlorate results for pregnant women ages 16–44 years to obtain a large number of pregnant women for comparison with the Vanguard Study sample results. Over these NHANES survey cycles, urinary perchlorate results for the U.S. population and for females appeared to be stable, with little variance in the geometric means and selected percentiles (CDC, 2015).

2.2 Vanguard Study Data collection

The prenatal study visit interview inquired about demographic characteristics, health conditions, medicines, environmental influences, and health-related behaviors. Age in years at the time of the study visit, race/ethnicity (non-Hispanic black, non-Hispanic white, Hispanic, other), income (<\$50,000, >=\$50,000), education (not high school graduate, high school graduate and/or some college, college graduate or higher), and self-reported thyroid disorder diagnosis were candidate predictors for the regression modeling. The interview also queried participants about their primary source of drinking water with response categories of tap, filtered tap, bottled, and other source. For two-thirds of participants, this question was asked at a study visit prior to the one in which they provided a urine sample.

Following the visit, participants completed a paper Food Frequency Questionnaire (FFQ), which was based on the NCI Diet History Questionnaire (Subar et al, 2001). The FFQ queried respondents about foods consumed over the past three months and the size of their usual portion.

Written informed consent was obtained from all participants and the study protocol was approved by the NICHD Institutional Review Board (IRB) and the IRBs at each Vanguard Study institution. The involvement of the CDC laboratory was determined not to constitute engagement in human subjects research.

2.3 NHANES pregnant women

Public-release NHANES files from 2001–2012 were used to obtain records for pregnant women ages 16–44 years who were identified by a positive pregnancy test result. Trimester of pregnancy was determined by response to the question "What month of pregnancy are you in?" Participants self-reported race/ethnicity (categorized as All Hispanic, non-Hispanic white, non-Hispanic black, and other), age at last birthday, and household annual income (categorized as < \$55,000 or >\$55,000). Education attainment was reported by category: not high school graduate, high school graduate and/or some college, college graduate or higher. The season of participation was categorized as winter/spring (11/1-4/30) or summer/fall (5/1-10/31). Pregnant women ages 16–44 years with urine perchlorate, SCN, and NO3 results comprised the analysis group.

2.4. Serum measurements

Blood was collected from Vanguard Study participants in serum separator tubes (SST tubes, Becton Dickinson; Franklin Lakes, NJ, USA) for thyroid measures and into no-additive serum red top tubes (Becton Dickinson; Franklin Lakes, NJ, USA) for serum cotinine. Samples were centrifuged locally at ambient temperature within 2 hours of collection and shipped on ice packs to the NCS repository. At the NCS repository, red top tubes were respun. Serum from the red top and SST tubes were aliquotted into pre-screened metal-free cryovials. Aliquots were stored using vapor phase liquid nitrogen (-196°C) until shipment on dry ice to the analytical laboratory. Quest Diagnostics Nichols Institute (San Juan Capistrano, CA, USA) analyzed serum samples for FT4 and TSH. The free direct dialysis method separates free T4 from protein-bound T4, and then FT4 is measured directly from the protein-free dialysate. TSH was measured using an immunochemiluminometric assay

(ICMA) method. Analytical sensitivities were 0.2 ng/dL (FT4) and 0.01 mIU/L (TSH). The laboratory's reference intervals for third trimester of pregnancy were 0.8-1.7 ng/dL for FT4 and 0.43-2.91 mIU/L for TSH. Serum cotinine was analyzed by the Environmental Health Laboratory at CDC using the method described by Bernert et al. (1997 and 2000). The limit of detection for serum cotinine was 0.015 ng/mL.

2.5. Urine measurements

NCS spot urine samples were collected into pre-screened, metal-free containers, frozen locally and shipped on dry ice to the NCS Repository (Fisher Bioservices, Rockville, MD) where urine was aliquotted into pre-screened metal-free cryovials and at stored at -80° C until shipment on dry ice to the CDC laboratory. NHANES spot urine samples were collected and aliquotted in the Mobile Examination Centers, and samples were shipped on dry ice to CDC's National Center for Environmental Health, where samples were stored at or below -20° C until analyzed. All urine measurements were performed by the Environmental Health Laboratory at CDC.

Perchlorate, thiocyanate and nitrate were analyzed by isotope dilution and ion chromatography/tandem mass spectroscopy (IC-MS/MS) using a slightly modified version of the method of Valentin-Blasini et al. (2007) and available at http://www.cdc.gov/nchs/ data/nhanes/nhanes 09 10/PERNT F met.pdf, 0.250 mL of urine was diluted to 1.0 mL with aqueous internal standard solution containing stable isotope labeled perchlorate (Cl¹⁸O₄⁻), thiocyanate (SC¹⁵N⁻), and nitrate (¹⁵NO₃⁻). Samples were vortex-mixed and queued for injection. Each analytical batch consisted of a blank, calibration standards, and four quality control (QC) samples (two QC low and two QC high). Analyte quantification was based on the peak area ratio of the analyte to stable isotope-labeled internal standard. Limits of detection (LOD) for measurements made from 2001–2012 were as follows: perchlorate 0.05 µg/L; NO3 0.7 mg/L; and SCN 0.02 mg/L. Iodine was measured by the method of Caldwell et al (2003 and 2005) that used inductively coupled plasma dynamic reaction cell mass spectrometry. Sample preparation used 0.5 mL of urine, diluted 1:10 with 1% (v/v) tetramethyl ammonium hydroxide, 0.2% Triton[™] X-100 (Mallinckrodt Baker, Inc., Phillipsburg NJ), 25 µg/L tellurium, 5 µg/L bismuth, 5% (v/v) ethanol, 1000 µg/L gold, and 0.5 g/L EDTA. Iodine quantification was based on the peak as a ratio of analyte to internal standard tellurium, and the LOD was 1.4 µg/L. Reported results for iodine, perchlorate and other anions met the accuracy and precision guidelines of the quality assurance/quality control program of the Division of Laboratory Sciences, National Center for Environmental Health, CDC (Caudill et al, 2008).

For NHANES 2001–2008, urine creatinine was measured based on the Jaffé rate reaction and performed on a Beckman CX3 Chemistry Analyzer (Beckman Instruments Inc., Brea, CA, USA). Details are available at http://www.cdc.gov/nchs/data/nhanes/nhanes_01_02/116_b_met_creatinine.pdf. Starting in 2009, urine creatinine was measured on a Roche/Hitachi Modular P Chemistry Analyzer, which employs an enzymatic method that is less susceptible to interferences from non-creatinine chromogens compared to older methods. Details are available at http://www.cdc.gov/NCHS/data/nhanes/nhanes_09_10/ ALB CR F met creatinine.pdf.

3.0 Data Analysis and Processing

3.1 NCS Dietary Data Processing

The FFQ analysis program, Diet*Calc 1.4.3, (NCI, 2013) transforms the FFQ responses to estimates of energy and nutrients (values taken from USDA's Food and Nutrient Database for Dietary Studies, FNDDS) and also food group equivalent values (values taken from the Center for Nutrition Policy and Promotion's MyPyramid Equivalent Database). Diet*Calc provides estimated consumption for dairy, total fruits, total vegetables, total fish, and total energy intake, among many other foods and nutrients. Values for dark green leafy vegetables, shellfish, and finfish were obtained from the USDA Food Commodity Intake Database (FCID) (U.S. EPA, 2010) and appended to Diet*Calc so we could estimate these intakes. The FCID converts foods in the USDA FNDDS database into corresponding retail commodities. The continuous food consumption variables were categorized into three groups: low consumers (<25th percentile), medium consumers (25th to 75th percentile), and higher consumers (>75th percentile) for presentation. For use in regression modeling to predict urinary perchlorate, thiocyanate, and nitrate, the continuous values were energy-adjusted, resulting in estimates of the grams or cup equivalents per 1,000 kcal consumed for each participant.

3.2 Statistical Analysis

Data were analyzed using Statistical Analysis System (SAS, version 9.3; SAS Institute, Inc., Cary NC). For both NCS and NHANES women, we calculated geometric means (GMs) and selected percentiles stratified by demographic factors, and other variables of interest. Unless otherwise specified, all reported concentrations are geometric means (GMs). The derived variable perchlorate equivalency concentration (PEC) was calculated based on work by Tonacchera et al (2004) and Bruce, et al (2013). The PEC calculation uses relative potencies of perchlorate, SCN, and NO3 inhibition of iodine uptake as determined *in vitro*. The PEC estimates the NIS inhibitory effects of the mixture of these anions, although these estimates may not be physiologically relevant *in vivo* because of the *in vitro* derivation that does not factor in gene expression or regulation and NIS transport to the basolateral surface of the human thyrocyte.

We examined factors associated with FT4 and TSH using multiple linear regression analysis. Serum TSH was log 10-transformed because the data were positively skewed. The variables included as predictors of FT4 and TSH were age, race/ethnicity (non-Hispanic black, non-Hispanic white, Hispanic, Other), education (not high school graduate, high school graduate/ some college, college graduate or more, unknown), income (<\$50,000, > \$50,000, unknown), smoking status (smoker >10 ng/mL; second hand smoke exposed 0.015 to <10 ng/mL; non-smoke exposed <0.015 ng/mL [< LOD]), study site, urinary iodine, thyroid disease status (not hypothyroid, hypothyroid and untreated, and hypothyroid and unknown if treated), and PEC. There were 23 women who reported current treatment for hypothyroidism and were excluded from this study.

To predict the urinary anions, we used stepwise regression with entry into the model set at p=0.20 and remain in model set at p=0.10. The candidate predictors for these models were

age, race/ethnicity, education, income, smoking status, study site, urinary creatinine, dietary variables (energy-adjusted consumption of leafy green vegetables, other vegetables, fruit, fish, and dairy), season of the year at time of study visit (winter = 12/20 to 3/19; spring = 3/20 to 6/19; summer = 6/20 to 9/19; fall = 9/20 to 12/19), primary drinking water source (bottled, filtered tap, unfiltered tap, or other), and cooking water source (bottled, filtered tap, unfiltered tap, or other). Final models included the resulting variables from the stepwise regression and, due to expected differences in the urinary anion concentrations by age, race/ethnicity, and location, these variables were included in the final models even if they did not meet the selection criteria. The urinary anions were log10-transformed because these data were positively skewed.

We also assessed correlations between log10 transformed urinary anions and iodine by calculating Pearson's correlation coefficients.

4.0 Results

4.1 Study Populations and Urinary Anion Distributions

4.1.1 NCS Women—There were 494 NCS pregnant women with urinary perchlorate, SCN, and NO3 results, after excluding the 23 who reported current treatment for hypothyroidism. Of these, 359 (73.1%) women also had FT4 and TSH results and 330 (66.3%) had urine and serum results and completed FFQ information. The demographic characteristics of these groups were similar: predominantly non-Hispanic white, college or higher educational attainment, and approximately half with annual household income of \$50,000 per year or greater (data for the full NCS sample shown in Table 1). These characteristics reflect the diverse geographic distribution as well as the rural and urban settings of the recruitment populations. The distribution of urine sample collections was approximately equal across spring, summer, fall, and winter (Supplemental Table 1). Urinary perchlorate, NO3, and SCN concentrations were similar in the NCS subsamples described above, but results are not shown.

Distributions of urinary perchlorate, SCN, and NO3 concentrations in the NCS women shown in Supplemental Table 1 were stratified by the potential covariates used in the regression modeling. Although the mean (95% CI) perchlorate concentration was somewhat higher in women from Utah (4.93 µg/L [4.21, 5.78]) and in samples collected in winter (5.21µg/L [4.39, 6.17]), there was little difference among the categories compared to the overall mean of 4.03 μg/L (3.72, 4.36). Although urinary perchlorate was higher in women who primarily used bottled water, the sources for drinking water were not mutually exclusive. Urine SCN concentrations were slightly higher in non-Hispanic black women (1.17 mg/L [0.71, 1.93]) and those reporting annual incomes $\leq 50,000 (1.03 \text{ mg/L} [0.90,$ 1.17]) compared to the overall mean (0.88 mg/L [0.81, 0.95]). Women with serum cotinine 10 ng/mL or higher had the highest SCN concentrations (4.57 mg/L [3.25, 6.43]), consistent with tobacco smoke as a source of cyanide exposure and increased urinary SCN. The overall mean urine NO3 (45.6 mg/L [42.9, 48.4]) was similar among the categories, with the exception of women with serum cotinine 10 ng/mL or higher (59.1 mg/L [47.4, 73.7]) and those from Utah (56.2 mg/L [49.0, 64.5]). These urine anion concentrations appeared similar to values observed in all females in NHANES cycles from 2001–2012 (CDC, 2015).

In the 359 women with serum TSH and FT4 results, the overall mean (95% CI) TSH was $1.46 \, \text{mIU/L}$ (1.37, 1.56) and the overall arithmetic mean FT4 was $1.11 \, \text{ng/dL}$ (1.08, 1.13) (Table 2). All FT4 and 95% of TSH values were within the laboratory reference range for third trimester women (FT4 $0.8-1.7 \, \text{ng/dL}$ and TSH $0.43-2.91 \, \text{mIU/L}$). TSH and FT4 were higher in younger women and in non-Hispanic white and Hispanic women but the numbers in other racial/ethnic groups were relatively small. These differences were not statistically significant at p<0.05.

Urine iodine results in this sample have already been described (Caldwell et al, 2013). The median concentration of 167 μ g/L provided evidence of adequate iodine intake, although there was variation across study sites, ranging from 107–217 μ g/L.

4.1.2. NHANES Pregnant Women—In NHANES 2001–2012, there were 533 pregnant women with urinary perchlorate, NO3, and SCN results. On average, there were fewer than 100 pregnant women in each NHANES 2-year cycle, too few to be representative of the U.S. population of pregnant women. Thyroid measurements were not available for all these NHANES survey periods so an analysis similar to that done in the NCS sample was not possible. Compared with the NCS sample, a higher percentage of NHANES women were ages 30–44 years, were Hispanic, and reported a lower education attainment; a majority (61.7 %) who reported household incomes had <\$55,000 per year (Table 1). Unlike the NCS sample, the NHANES women were distributed across all the trimesters.

Urinary perchlorate results were similar in the NCS and pregnant NHANES women (Table 1). The overall means (95% CI) were 4.04 μ g/L (3.74, 4.37) in NCS and 3.58 μ g/L (2.98, 4.18) in NHANES women, and the interquartile ranges (IQRs) were similar for both groups. The NCS winter/spring mean (4.61 μ g/L [4.15, 5.12]) was higher than the NHANES mean (3.44 μ g/L [2.73, 4.16]). Urinary perchlorate concentrations appeared to be similar across trimesters in the NHANES women: 3.99 (2.35, 5.62), 2.96 (2.26, 3.67), and 3.27 (2.59, 3.95) μ g/L in the first, second, and third trimesters, respectively.

4.2 Correlations Between Urinary Anions and Iodine in NCS Women

Log-transformed perchlorate, NO3, and iodine were significantly correlated with each other, with correlation coefficients (r) ranging from 0.45 to 0.51. Log-transformed SCN was less strongly correlated with the other analytes; r=0.14 with log10 perchlorate, r=0.35 with log10 nitrate, and r=0.33 with log10 iodine.

4.3 Predictors of Urinary Perchlorate, SCN, and NO3 in NCS Women

4.3.1 Dietary Intakes and Urinary Anions—For the NCS pregnant women who also had complete dietary information available, Supplemental Table 2 shows mean and selected percentiles for each urinary anion, stratified by food categories and reported dietary intakes. No relationship was apparent between mean perchlorate concentrations and any dietary intake. Urinary SCN and NO3 concentrations increased with total vegetable intakes and decreased with total fruit intakes. Urinary SCN concentrations increased with leafy green vegetable intake; whereas, urine NO3 mean concentrations decreased slightly with total dairy intake. No other relationships between intakes and anion concentrations were apparent.

4.3.2 Regression Analyses—In models to examine predictors for each log-transformed anion, the food intakes were energy adjusted; that is, the amount consumed was divided by total calories, then multiplied by 1000 (to provide intake per 1000 kCal). Significant predictors (at p<0.05) of log10 transformed urinary perchlorate were race/ethnicity, study site, season, drinking water source, leafy green vegetable intake, and log10 urinary creatinine. Adjusted GM urinary perchlorate was highest in Hispanic women (5.07 µg/L [3.90, 6.60]) compared to other racial/ethnic categories, in women from Wisconsin (4.88 μg/L [3.59, 6.64]) compared to the other study sites, in women who were sampled in winter (4.10 μg/L [3.20, 5.26]), and in women who reported drinking bottled water (4.17 μg/L [3.41.5.10]). Leafy green vegetable intake was associated with increased urinary perchlorate concentrations, with each additional g/1,000 kCal resulting in an increase of 0.005 in the log10 urinary perchlorate concentration (Table 3). Significant predictors of log10 transformed urinary SCN were age, race/ethnicity, log10 urinary creatinine, smoking status, study site, and intakes of total fruits and leafy green vegetables. Adjusted GM SCN concentrations were higher in non-Hispanic blacks and whites (1.23 mg/L [0.83, 1.84] and 1.27 mg/L [1.09, 1.47], respectively) compared to Hispanic and other racial/ethnic categories and highest in women with serum cotinine >10 ng/mL (3.51 mg/L [2.44, 5.06]). Women from Montgomery, PA had the lowest adjusted GM SCN concentrations (0.70 mg/L [0.52, 0.95]) and women from Orange, CA and Salt Lake, UT had the highest (1.32 mg/L [0.98, 1.76] and 1.28 mg/L [1.01, 1.63]), Leafy green vegetable intake was associated with increasing SCN concentrations, and age and fruit intake were inversely related to urinary SCN (Table 3). Significant predictors of log10 transformed urinary NO3 were study site, leafy green vegetable intake, and log10 urinary creatinine. Women from Waukesha, WI and Salt Lake, UT had the highest adjusted GM SCN concentrations (52.3 mg/L [44.3, 61.9] and 51.8 [44.9, 59.7], respectively) and women from Duplin, NC had the lowest (37.8 [33.3, 42.9]. Leafy green vegetable intake was associated with increasing urinary NO3 concentrations.

Neither PEC nor iodine were significant predictors of thyroid function (Table 4). Replacing PEC in the models with perchlorate or the creatinine-adjusted PEC or perchlorate resulted in similar findings (data not shown). No predictor was significant at p<0.05 of either FT4 or log10 transformed TSH. These results were unchanged when we examined only women with urinary iodine $<100 \ \mu g/L$ (data not shown).

5.0 Discussion

Neither urinary perchlorate nor PEC were predictive of TSH or FT4 in the NCS women, regardless of urinary iodine concentration. Our results are similar to studies of first trimester women that found no association between perchlorate exposure or PEC and TSH or FT4, even when urine iodine was <100 μ g/L (Pearce et al, 2010, 2011, and 2012; Tellez et al, 2005). In contrast, urinary perchlorate was predictive of increased TSH and reduced FT4 in first trimester Thai women (Charatcharoenwitthaya et al, 2014) and in pregnant women exposed via contaminated drinking water (Steinmaus, et al, 2015). Studies using NHANES data also have had inconsistent findings: urinary perchlorate or PEC were not predictive of TSH or T4, even in women with urinary iodine < 100μ g/L (Bruce et al., 2013); whereas high urinary perchlorate alone (Blount et al, 2006; Mendez et al, 2012) or in combination with

high SCN was associated with significantly lower T4 and/or TSH in individuals with urinary iodine $< 100 \mu g/L$ (Steinmaus et al, 2013). NHANES data also provided evidence that smoking, with subsequent higher urinary SCN, may interact with perchlorate to affect thyroid function, especially in women with urinary iodine $< 100 \mu g/L$ (Steinmaus et al, 2007).

Differences in thyroid hormone analytical methods and pregnancy-related hormonal changes, in addition to study design and sample differences, may contribute to differences in various study results. Immunologic assays for total thyroxine (T4) and FT4 were subject to biases from pregnancy-related serum protein changes and may not be sufficiently precise (Steele et al, 2005). The method used in the present study, which employs equilibrium dialysis, separates free from protein bound thyroxine so that the free concentration can be measured directly (Thienpont et al, 2013). In fact, the variability and lack of comparability of FT4 and TSH results obtained from different analytical methods is a recognized clinical interpretation challenge (Thienpont et al, 2015). During pregnancy, thyroid hormones increase by about 50% and TSH decreases, particularly in the first trimester (Stagnaro-Green et al, 2011). Thus, changing hormone concentrations during pregnancy in addition to variability in thyroid hormone measurements may obscure effects of low level environmental exposures.

We expected urinary perchlorate concentrations to increase with consumption of leafy green vegetables and dairy, but when intakes were adjusted for race/ethnicity, study location, and season, only leafy green vegetable consumption was a significant predictor. These results are consistent with an analysis of perchlorate sources in the U.S. diet (Murray et al., 2008). That the adjusted GM urinary perchlorate was highest in Hispanic compared to other racial/ethnic categories is likely the result of dietary differences, but the small subsample size limited further analysis. The highest adjusted urinary perchlorate concentrations were observed in winter, possibly because fresh vegetables available and consumed at that time of year came from arid regions where perchlorate from natural and anthropogenic sources result in higher food crop levels (English et al, 2011; Sanchez et al, 2008 and 2009). Leafy green vegetable intake was predictive of urine SCN, consistent with the observation that various foods, including root and cruciferous vegetables (e.g., kale, broccoli, cauliflower) contain SCN or cyanide that is subsequently metabolized to SCN (Clements, 1960). In addition, all three anions and iodine were highly correlated, most likely because they are concentrated by similar mechanisms in the food supply and share dietary sources, so it is not surprising that leafy green vegetable intake was associated with higher concentrations of all three anions. Defined as serum cotinine 10 ng/mL or higher, smoking was highly predictive of urine SCN, but there were few smokers in the NCS sample. Somewhat unexpectedly, bottled water was predictive of higher urinary perchlorate, but the interview question asked primary source and did not include sufficient detail to permit any apportionment across drinking water sources. Ours may be a chance finding, or possibly, women residing where naturally-occurring perchlorate is present in the water may be aware and so avoid tap water for most but not all of their consumption.

Urinary perchlorate concentrations in this large sample of third trimester NCS women were similar to concentrations in similar-aged pregnant women who participated in NHANES

2001–2012, and both groups had concentrations similar to those of all females in the U.S. population (CDC, 2015). Means (95% CI) were similar in the three groups: NCS, 4.03 μ g/L (3.72, 4.36); pregnant women in NHANES, 3.58 μ g/L (2.98, 4.18); and all females (6+ years) in NHANES 2001–2012, ranging from 2.65 to 3.42 μ g/L (CDC, 2015). Urinary SCN and NO3 means in the NCS women also were similar to those of all U.S. females in NHANES: NO3, 45.6 mg/L (42.9, 48.4) vs. a range of 37.1 to 41.4 mg/L; SCN, 0.88 mg/L (0.81, 0.95) vs. a range of 0.93 to 1.26 mg/L, respectively. Pregnancy did not appear to alter exposure to perchlorate or the other anions. The few NCS women who were smokers (N=30 with serum cotinine >10 ng/mL [Supplemental Table 1]) had mean urinary SCN that was similar to U.S. adult women smokers: 4.57 mg/L (3.25, 6.43) vs. 4.19 mg/L (3.81, 4.61), respectively (CDC, 2015).

Study design and methodology differences may contribute to different findings in the studies of perchlorate exposure and thyroid function in pregnant women. It is also possible that environmental perchlorate exposures in the U.S., even when SCN and NO3 are considered, may be near or below a threshold that produces measurable thyroid effects in healthy pregnant women. (Given the critical role of adequate thyroid hormone for conception and pregnancy, we consider these study populations of pregnant women to be in good overall health, regarding thyroid status, at least.) Even those studies showing negative effects on TSH and FT4 are difficult to interpret clinically, because of physiologic changes in thyroid indicators during pregnancy and the different and relatively wide span of reference range values (Medici et al, 2015; Stagnaro-Green et al, 2011). For example, the clinical laboratory that analyzed our samples reported reference values for TSH of 0.26–2.66 mIU/L (first trimester), 0.55–2.73 mIU/L (second trimester), and 0.43–2.91 mIU/L (third trimester). Similar reference values for FT4 were 0.9–2.0 ng/dL (first trimester), 0.8–1.5 ng/dL (second trimester), and 0.8–1.7 ng/dL (third trimester) (Quest Diagnostics, 2015 http:// www.questdiagnostics.com/home.html). This can make it difficult to infer clinical significance of statistically significant but small changes in thyroid indicators.

Strengths of the present study include the large sample of women at a similar stage of pregnancy and quality of the laboratory methods for measuring thyroid function. We were able to use third trimester-specific TSH and FT4 reference intervals and avoid the early pregnancy-related variability in these measures (Stagnaro-Green et al, 2011). The direct dialysis method used to measure FT4 in the NCS women has greater specificity than immunoassay methods (Sapin et al, 2003; Thienpont et al, 2013). Although ours was a convenience sample, the NCS women were geographically, economically, and racial/ethnically diverse, and the relatively large sample size extends the literature on perchlorate and other anion exposures in pregnancy.

Noteworthy limitations include the FFQ and single "spot" measures of anion exposure and thyroid indicators. The NCS used a FFQ questionnaire that was based on the National Cancer Institute's Dietary History Questionnaire and asked about intakes during the previous 3 months, so recall bias and inaccurate reporting were possible but would have been random in these generally healthy women. The urinary anions measured are rapidly eliminated after entering the body, so the measurements indicate recent exposure. However, because diet was

the major exposure source, assuming that contributory food intakes are relatively consistent and recurrent is reasonable, the urinary anion concentrations may not fluctuate greatly.

6.0 Conclusions

Neither urine perchlorate nor PEC was a predictor of TSH or FT4, even in NCS women with urinary iodine $<100~\mu g/L$. Environmental perchlorate exposure may be below a threshold for clinically-detectable thyroid effects in pregnancy. We restricted our sample to third-trimester women in whom FT4 was measured using a highly accurate analytical method. Inattention to trimester-specific ranges may affect study results involving pregnant women across different trimesters, when thyroid hormone and TSH concentrations can change dramatically. Dietary sources were the major sources of perchlorate, NO3, and SCN in non-smokers. Urinary perchlorate concentrations in the NCS third trimester women were similar to those in pregnant women in NHANES 2001–2012.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Highlights

1. Limited biomonitoring data are available in pregnant women, and we report results of perchlorate, thiocyanate, and nitrate measurements in 494 third trimester women.

- 2. We found no effect of perchlorate and related anions on the thyroid indicators, TSH and free T4, regardless of urinary iodine concentration, in a large sample of third trimester women.
- **3.** Leafy green vegetables were a common dietary source for perchlorate, nitrate, and thiocyanate.

 $\label{eq:Table 1} \textbf{Table 1}$ Demographics and Urinary Perchlorate Concentrations (µg/L) in Pregnant Women Ages 16–44 Years in the NCS and NHANES, 2001–2012

		NCS W	omen		NHANES Women					
		Geometric Mean	Percentiles			Geometric Mean	Percentiles			
Category	N	(95% CI)	IQR	50th 95th		N	(95% CI)	IQR	50th	95th
Total	494	4.03 (3.72,4.36)	4.35	4.0	17.5	533	3.58 (2.98, 4.18)	4.22	3.3	20.3
Women with Thyroid Results	359	4.04 (3.68,4.44)	3.88	4.0	18.1					
Age, years										
16 to 29	258	4.21 (3.79,4.68)	4.25	4.0	17.7	368	3.52 (2.94, 4.10)	4.45	3.4	15.4
30 to 44	236	3.84 (3.41,4.32)	4.40	3.8	17.5	165	3.65 (2.69, 4.62)	3.55	3.3	29.1
Race/Ethnicity										
Hispanic	99	4.54 (3.77,5.46)	5.30	4.6	23.0	170	4.14 (3.1, 5.19)	4.88	4.5	20.2
Non-Hispanic white	318	4.05 (3.66,4.47)	4.14	4.0	17.5	209	3.81 (2.84, 4.78)	3.94	3.3	14.2
Non-Hispanic black	30	3.15 (2.48,4.01)	2.39	3.1	10.4	92	3.14 (2.27, 4.02)	4.09	3.2	14.7
Other	47	3.54 (2.79,4.50)	5.22	3.7	10.8	62	2.9 (0.95, 4.84)	4.54	2.7	29.8
Education										
Not high school graduate	77	3.88 (3.14,4.79)	4.01	3.8	18.7	174	4.02 (2.96, 5.08)	5.54	4.9	14.9
High school or some college	213	4.06 (3.65,4.50)	3.85	4.1	13.1	254	3.44 (2.49, 4.38)	4.39	3.3	26.7
College graduate or more	200	4.04 (3.52,4.64)	4.95	3.8	24.4	105	3.51 (2.60, 4.42)	3.00	2.9	14.0
Unknown	14									
Annual Income						***************************************				***************************************
< \$50,000	224	4.07 (3.62,4.57)	4.06	4.0	17.7		as 20			
≥ \$50,000	224	4.06 (3.60,4.59)	4.53	4.0	17.5					
Unknown	46	3.67 (2.91,4.63)	3.87	3.8	13.1	126				
<\$55,000						313	3.49 (2.68, 4.31)	4.47	3.3	25.0
≥ \$55,000						194	3.58 (2.69, 4.47)	3.90	3.3	20.1

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		NCS W	omen		NHANES Women						
		Geometric Mean	Perce	ntiles		Geometric Mean	Percentiles				
Category	N	(95% CI)	IQR	50th 95th		N	(95% CI)	IQR	50th	95th	
Season											
Winter/Spring (Nov. 1-April 30)	257	4.55 (4.09,5.07)	4.46	4.2	18.2	278	3.44 (2.73, 4.16)	3.89	3.3	27.9	
Summer/Fall (May 1-Oct.31)	237	3.52 (3.15,3.95)	3.86	3.3.6	13.1	255	3.69 (2.75, 4.64)	4.24	3.9	20.0	
² Trimester											
First						100	3.99 (2.35, 5.62)	4.28	4.8	28.4	
Second						187	2.96 (2.26, 3.67)	3.62	2.9	16.4	
Third	494	4.03 (3.72,4.36)	4.35	4.0	17.5	172	3.27 (2.59, 3.95)	3.08	3.2	12.0	

¹Too few results to calculate.

Table 2
Serum Free T4 and TSH Results in NCS Third Trimester Pregnant Women

		Serum Free T4 (Thyroxi	Serum Thyroid Stimulating Hormone, mIU/L						
	N	Arithmetic Mean (95% CI)	IQR	50th	95th	Geometric Mean (95% CI)	IQR	50th	95th
Women with perchlorate & thyroid results	359	1.11 (1.08,1.13)	0.30	1.10	1.50	1.46 (1.37,1.56)	1.03	1.50	3.82
Age (years)									
16 to 29	189	1.11 (1.07,1.14)	0.30	1.10	1.40	1.46 (1.33,1.61)	0.97	1.47	3.97
30 to 44	170	1.10 (1.06,1.14)	0.30	1.10	1.60	1.46 (1.34,1.59)	1.09	1.58	3.35
Race/Ethnicity									
Hispanic	72	1.09 (1.03,1.15)	0.30	1.10	1.60	1.50 (1.31,1.72)	1.09	1.60	3.77
Non-Hispanic white	231	1.10 (1.07,1.13)	0.30	1.10	1.40	1.49 (1.37,1.63)	1.07	1.53	3.83
Non-Hispanie black	22	1.07 (0.97,1.16)	0.40	1.10	1.40	1.36 (1.07,1.73)	1.00	1.51	2.20
Other	34	1.18 (1.09,1.26)	0.30	1.20	1.50	1.26 (1.05,1.51)	0.64	1.23	2.99

Third trimester reference ranges: FT4 0.8-1.7 ng/dL; TSH 0.43-2.91 mIU/L

ED_005043_00027766-00021

Table 3

Regression Results for Urinary Perchlorate, Thiocyanate, and Nitrate in Third Trimester NCS Women

		Perch	lorate (μg/L)		Thiocyanate (mg/L)			Nitrate (mg/L)		
	β^b	p-value	Geo. Mean ^c (95% CI)	β^b	p-value	Geo. Mean ^c (95% CI)	β^{b}	p-value	Geo. Mean ^c (95% CI)	
All NCS Women (N=329 ^a)			4.12 (3.73,4.55)			0.88 (0.79,0.97)			45.8 (42.7,49.1)	
Race/Ethnicity		0.003			0.04			0.46		
Non-Hispanic Black			2.26 (1.43,3.59)			1.23 (0.83,1.84)			40.74 (31.54,52.62)	
Hispanic			5.07 (3.90,6.60)			0.92 (0.72,1.16)			50.52 (44.11,57.85)	
Non-Hispanic White			3.34 (2.74,4.06)			1.27 (1.09,1.47)			46.21 (42.05,50.78)	
Other			3.15 (2.19,4.52)			0.91 (0.67,1.23)			48.34 (39.79,58.73)	
Education		0.06						0.20		
Not high school graduate			2.70 (1.97,3.72)						49.04 (41.23,58.33)	
High school graduate or some college			3.32 (2.66,4.13)						43.21 (38.72,48.22)	
College graduate or more			4.06 (3.19,5.17)						46.86 (41.70,52.65)	
Study Site		0.002			0.01			0.02		
BYPL, SD, MN			4.12 (3.13,5.43)			1.14 (0.90,1.44)			45.73 (39.55,52.87)	
Duplin, NC			2.38 (1.84,3.08)			1.06 (0.86,1.29)			37.80 (33.33,42.86)	
Montgomery, PA			3.42 (2.40,4.88)			0.70 (0.52,0.95)			45.79 (37.87,55.37)	
Orange, CA			3.20 (2.28,4.50)			1.32 (0.98,1.76)			46.63 (38.88,55.93)	
Queens, NY			2.15 (1.37,3.37)			1.05 (0.72,1.55)			45.65 (35.67,58.41)	
Salt Lake, UT			3.91 (2.97,5.14)			1.28 (1.01,1.63)			51.76 (44.85,59.73)	
Waukesha, WI			4.88 (3.59,6.64)			1.06 (0.80,1.40)			52.34 (44.30,61.85)	
Smoking Status (defined by serum cotinine)					<.0001					
≥10 ng/ml						3.51 (2.44,5.06)				
0.015 to <10 ng/ml						0.73 (0.60,0.89)				
<0.015 ng/ml)						0.71 (0.60,0.84)				
Missing						0.72 (0.58,0.89)				
Season		0.01								
Fall			2.74 (2.12,3.53)							
Spring			3.31 (2.59,4.23)							
Summer			3.25 (2.53,4.17)							

	Perchlorate (μg/L)				Thiocyanate (mg/L)			Nitrate (mg/L)		
	β^b	p-value	Geo. Mean ^c (95% CI)	β <i>b</i>	p-value	Geo. Mean ^c (95% CI)	β^b	p-value	Geo. Mean ^c (95% CI)	
Winter			4.10 (3.20,5.26)							
Drinking Water Source		0.03								
Bottled			4.17 (3.41,5.10)							
Filtered tap			3.02 (2.46,3.70)			***				
Other			2.67 (1.59,4.48)							
Unfiltered tap			3.60 (2.89,4.50)					***	∞ ≥ ∞	
Age (years)	-0.003	0.37		-0.007	0.030		-0.0003	0.90		
Leafy Green Vegetable intake (g/1000kCal)	0.005	0.003		0.005	0.001		0.003	0.005		
Fruit intake (cups/1000kCal)				-0.055	0.002					
Vegetables intake (cups/1000kCal)										
Dairy intake (cups/1000kCal)										
Urine creatinine (log-transfromed)	0.651	<.0001		0.533	<.0001		0.711	<.0001		

^aOne individual with mising data from drinking water source was excluded from the analysis.

b coefficient presented for continuous variables. A one unit change in the predictor variable results in a change the size and direction of the estimate in the log 10-transformed urinary analyte.

 $^{^{\}it c}_{\rm Least}$ squares means from regression modeling for categorical variables

 Table 4

 Regression Results for Serum Free T4 and Thyroid Stimulating Hormone in Third Trimester NCS Women

_		Serum F	ree T4, ng/dL	Serum log10(TSH, mIU/mL)				
-	β <i>a</i>	p-value	Arith. Mean ^b (95% CI)	β <i>a</i>	p-value	Geo. Mean ^b (95% CI)		
All NCS Women (N=359)			1.11 (1.08,1.13)	***************************************		1.46 (1.37,1.56)		
Age (years)	-0.005	0.06		-0.002	0.47			
Race/Ethnicity		0.05			0.47			
Non-Hispanic Black			1.02 (0.87,1.17)			1.63 (1.11,2.41)		
Hispanic			1.02 (0.89,1.14)			1.72 (1.24,2.39)		
Other			1.18 (1.05,1.31)			1.53 (1.09,2.14)		
White			1.09 (0.98,1.19)			1.87 (1.42,2.46)		
Education		0.05			0.70			
Not high school graduate			1.25 (1.09,1.41)			1.97 (1.31,2.98)		
High school graduate or some college			1.19 (1.04,1.34)			1.92 (1.31,2.80)		
College graduate or more			1.22 (1.07,1.38)			1.77 (1.18,2.65)		
Unknown			c					
Annual Income		0.97			0.09			
<\$50,000			1.08 (0.96,1.19)			1.49 (1.12,2.00)		
Unknown			1.08 (0.95,1.21)			2.01 (1.43,2.82)		
>=\$50,000			1.07 (0.95,1.19)			1.59 (1.16,2.19)		
Smoking Status (defined by serum cotinin	e)	0.74			0.83			
≥10 ng/ml			1.09 (0.95,1.23)			1.52 (1.06,2.18)		
0.015 to <10 ng/ml			1.05 (0.94,1.16)			1.69 (1.27,2.24)		
<0.015 ng/ml)			1.08 (0.98,1.19)			1.69 (1.30,2.20)		
Missing			1.07 (0.90,1.25)			1.86 (1.18,2.93)		
${\bf Hypothyroidism}^d$		0.07			0.23			
Yes, not treated			0.89 (0.67,1.12)			1.87 (1.05,3.36)		
No			0.97 (0.85,1.10)			1.30 (0.94,1.80)		
Unknown			1.36 (1.08,1.63)			1.96 (0.97,3.96)		
Study Site		0.46			0.11			
BYPL, SD, MN			1.05 (0.92,1.18)			1.55 (1.12,2.16)		

		Serum F	ree T4, ng/dL	Serum log10(TSH, m1U/mL)					
	β <i>a</i>	p-value	Arith. Mean ^b (95% Cl)	β ^a	p-value	Geo. Mean ^b (95% CI)			
Duplin, NC			1.07 (0.96,1.19)			1.67 (1.24,2.25)			
Montgomery, PA			1.10 (0.96,1.24)			1.76 (1.24,2.51)			
Orange, CA			1.14 (1.01,1.26)			1.42 (1.02,1.98)			
Queens, NY			1.02 (0.88,1.16)			1.79 (1.26,2.55)			
Salt Lake, UT			1.05 (0.93,1.17)			2.03 (1.50,2.76)			
Waukesha, WI			1.10 (0.96,1.24)			1.63 (1.13,2.36)			
Urinary iodine ^e	-0.00005	0.50		0.00006	0.48				
Urinary PEC ^e	0.00007	0.10		-0.00008	0.10				

^aβ coefficient presented for continuous variables. A one unit change in the predictor variable results in a change the size and direction of the estimate in FT4 and the log 10-transformed TSH.

 $[\]stackrel{b}{\text{Least}}$ squares means from regression modeling for categorical variables

cn<10, data redacted

 $[\]frac{d}{23}$ women who reported treatment for hypothyroidism were excluded from the analysis

 $^{^{}e}$ Using creatinine corrected urinary iodine and PEC yielded similar results.

Message

From: Hernandez-Quinones, Samuel [Hernandez.Samuel@epa.gov]

Sent: 4/2/2018 3:27:06 PM

To: Burneson, Eric [Burneson.Eric@epa.gov]

CC: Huff, Lisa [Huff.Lisa@epa.gov]; Christ, Lisa [Christ.Lisa@epa.gov]

Subject: RE: Status of the Peer Review Report

Attachments: Panel 2 Post-meeting Comment Report_Final.pdf

Hi Eric,

We received the final Peer Review report on Friday. See attached.

Once I get clearance from Lisa I will post to the Docket. We have also drafted an update to the perchlorate website to announce the availability of the report. We also intend to simultaneously send an email blast to the EPA working group as well as to all the attendees to the public meeting announcing the availability.

Let me know if you have any questions or comments.

Thanks

Sam

Samuel Hernández Quiñones, P.E.
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"USEPA Protecting Human Health and the Environment"

From: Burneson, Eric

Sent: Monday, April 02, 2018 11:21 AM

To: Huff, Lisa < Huff.Lisa@epa.gov>; Christ, Lisa < Christ.Lisa@epa.gov> **Cc:** Hernandez-Quinones, Samuel < Hernandez.Samuel@epa.gov>

Subject: Status of the Peer Review Report

Lisa:

What is the status of our peer review report for perchlorate. When do we expect to post it to the web?

Eric Burneson, P.E.

Director of Standards and Risk Management Office of Ground Water and Drinking Water U.S. Environmental Protection Agency 202 564 5250

Post-Meeting Peer Review Summary Report

External Peer Review for EPA's Proposed Approaches to Inform the Derivation of a Maximum Contaminant Level Goal for Perchlorate in Drinking Water

March 2018

Peer Reviewers:

Hugh A. Barton, Ph.D. Nancy Carrasco, M.D., M.S. Jonathan Chevrier, Ph.D. Claude Emond, Ph.D. Dale Hattis, Ph.D.
Angela M. Leung, M.D., M.Sc.
Stephen M. Roberts, Ph.D.
Joanne F. Rovet, Ph.D.

Contract No. EP-C-13-010 Task Order 2015-22



Prepared for:

U.S. Environmental Protection Agency Office of Ground Water and Drinking Water, Standards and Risk Management Division, 1200 Pennsylvania Avenue NW (MC 4607M) Washington, DC 20460



Prepared by:

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EXECUTIVE SUMMARY

Versar, Inc. (Versar), a contractor for the U.S. Environmental Protection Agency (EPA), coordinated an external peer review of EPA's scientific assessment titled "Draft Report: Proposed Approaches to Inform the Derivation of a Maximum Contaminant Level Goal for Perchlorate in Drinking Water" (MCLG Approaches Report) that links EPA's revised perchlorate Biologically Based Dose-Response (BBDR) model predictions to neurodevelopmental effects to inform decision-making for perchlorate under the Safe Drinking Water Act. As part of the peer review of the MCLG Approaches Report and revised BBDR model, Versar organized a two-day public peer review meeting in Arlington, Virginia on January 29-30, 2018. The peer review was initiated with a pre-meeting written peer review managed by Versar and conducted by eight independent expert peer reviewers. The role of the peer reviewers was to evaluate the scientific and technical merit of the MCLG Approaches Report and revised BBDR model, and provide their responses to fifteen charge questions. Peer reviewers were responsible only for evaluating the quality of the science included in EPA's MCLG Approaches Report and revised BBDR model, and were not asked to make any regulatory recommendations or to reach consensus in either their deliberations or written comments. The two-day peer review meeting, which directly followed the written peer review period, was held to discuss the scientific basis supporting EPA's MCLG Approaches Report and revised BBDR model and to provide members of the public with an opportunity to make brief oral statements and observe the peer reviewer deliberations.

On the first day of the meeting, Versar began by providing information on the overall peer review process and introducing the peer reviewers. Following a welcome by EPA, authors from EPA provided background information on the MCLG Approaches Report and revised BBDR model. Next, an observer comment session was held, after which the peer reviewers began their discussions. The discussion was moderated by the Chair, Dr. Stephen Roberts, and focused on individual responses to EPA's charge questions. The second day of the meeting began with brief remarks from Versar and EPA and then continued with discussion of responses to the charge questions.

Following the meeting, peer reviewers were given additional time to complete their individual written reviews, which were submitted to Versar upon completion. These final written comments (contained in Sections 2 through 7 of this report) fall into three categories: general impressions, responses to charge questions, and specific observations. Written peer review comments, as well as comments submitted to the docket by members of the public, will be considered by EPA as it revises the MCLG Approaches Report.

Important discussion points at the meeting, developed by Dr. Roberts with assistance from the entire peer review panel, are summarized below by charge question. The discussion points highlight recommendations reached by the panel, as derived from those experts expressing an opinion.

General Impressions

The panel commends EPA for the substantial amount of work done in creating the new modeling and preparing the report under review. It was highly responsive to the review comments from a year ago. Overall, the panel agreed that the EPA and its collaborators have prepared a highly innovative state-of-the-science set of quantitative tools to evaluate neurodevelopmental effects that could arise from drinking water exposure to perchlorate. While there is always room for improvement of the models, with limited additional work to address the committee's comments below, the current models are fit-for-purpose to determine an MCLG. As always with a scientific methodology of this complexity, it is important for EPA to focus on communications so that stakeholders can understand, as clearly as possible, the analyses that are done and the conclusions that are drawn.

Topic 1. General Questions

Charge Question 1: Appropriateness of focusing the current evaluation on perchlorate's potential impact on the fetus of hypothyroxinemic pregnant women during early gestation

The panel is in agreement that the focus of the current assessment on early gestation is appropriate. The previous version of the model, peer-reviewed in January 2017, evaluated perchlorate impact on thyroid hormones in late gestation and early infancy, including infants who are breast fed and those who are fed formula prepared with perchlorate-contaminated water. The peer review panel at that time pointed out that the first trimester fetus may be the most sensitive life stage and strongly recommended that it be included in the modeling. The current version of the model is responsive to that recommendation.

Although there is panel agreement that a focus on early gestation is appropriate, it will be important to also address the other sensitive life stages in some manner when developing the MCLG. A number of key processes for neurodevelopment that are thyroid dependent come on line past the second trimester and therefore are not captured in this model. The need for thyroid hormone varies among different brain regions, thus giving rise to different abilities and different deficits depending upon when thyroid hormone is lacking. The panel agrees with EPA that data with which to establish a quantitative linear relationship between perchlorate exposure and adverse neurodevelopmental effects for other sensitive life stages is more limited than that which exists for first trimester exposures, and this may effectively preclude extending the BBDR model to other life stages. If this is the case, a rationale will be needed to justify why an MCLG based upon protection of the first trimester fetus is in fact protective of all of the sensitive life stages identified previously. The panel has no recommendation on how this justification might be approached, but potential use of the model of perchlorate effects on thyroid hormone in late gestation and early infancy (i.e., the breast fed and formula fed infant) peer reviewed last year was discussed.

Charge Question 2: Additional peer-reviewed studies that could inform the BBDR modeling

Drs. Rovet and Leung have suggestions for additional peer-reviewed studies that could inform BBDR modeling of the quantitative relationship between thyroid hormone levels to neurodevelopmental outcomes. Those suggestions appear in their individual comments.

<u>Topic 2. BBDR Modeling to Predict Changes in Thyroid Hormone Levels in Early Pregnancy</u>

Charge Question 3a: Determination of the quantitative relationship between oral intake and serum levels of perchlorate during pregnancy

There was panel agreement that the model reasonably captures the quantitative relationship between oral perchlorate intake and perchlorate levels during pregnancy, and that the model and assumptions were appropriate.

Charge Question 3b: Estimating statistical distributions of specific parameters

The approaches for estimating statistical distributions were considered appropriate with two exceptions regarding variability in maternal fT4:

- 1) In the report, data were assumed to be lognormally distributed and variability was quantified by a geometric standard deviation (GSD). GSD values were averaged, which is not appropriate. The variances should be averaged instead.
- 2) The assumption of lognormality is influential and appears to create counterintuitive modeling results (see response to Charge Question 13). The use of other right-skewed distributions or a normal distribution should be explored.

Charge Question 4: Uncertainty analysis of model parameters

During panel discussion, no concerns were expressed regarding the uncertainty analysis of model parameters.

Charge Question 5: Utility of the model for predicting variability in fT4 levels in the population

NHANES data and results from a variety of studies clearly indicate that fT4 levels are quite variable among individuals within the population, and it is important for the BBDR model to capture this variability. The panel briefly discussed contributors to this variability and technical challenges in establishing the relationship between dietary iodide and fT4 levels (e.g., issues with fT4 measurement and the ability to predict dietary intake on a relevant time scale from spot urine iodide samples). Regardless the causes for variability, the BBDR model appears to predict it reasonably well (Figure A-57), and no concerns were expressed regarding the utility for estimating fT4 variability at various levels of iodide intake.

Charge Question 6: Robustness, precision, and sensitivity of the model

The panel noted the limited data with which to assess the robustness, precision, and sensitivity of the model in predicting fT4 changes at low perchlorate doses. The EPA provides a comparison of model outputs with data from Steinmaus et al. in Appendix B, but a number of aspects of this study (e.g., non-concurrent measurement of perchlorate exposure and fT4 levels, uncertainties associated with spot urine perchlorate measurements as an indicator of the level of perchlorate exposure) limit its value for this purpose. Nevertheless, the panel considered the model adequate for the purpose of characterizing perchlorate effects on fT4 during the first trimester of pregnancy and did not identify a perchlorate dose range for which the modeling results would be highly uncertain.

Charge Question 7: Assumptions, strengths and limitations of the TSH feedback loop; availability of other studies for TSH feedback loop; approach to characterizing interindividual variability

The panel agreed that inclusion of the TSH feedback loop is an important addition to the BBDR model. Suggestions for aspects of the model where further clarification or discussion is needed are provided in the individual panel member comments.

The panel is not aware of other studies besides Hadlow et al. (2013) that should be considered in describing the relationship between fT4 and TSH. However, the panel noted that a log-linear relationship between fT4 and TSH is well established both historically and in the recent literature. There was agreement that the rationale for using the empirical relationship from Hadlow et al. versus the traditional lognormal relationship merits additional discussion in the report.

Charge Question 8: Accounting for exposure to other goitrogens

EPA has assumed that exposure to other goitrogens is accounted for implicitly in the model because the population used to inform and calibrate the model had exposures to these other goitrogens. The effect of perchlorate is then modeled over and above this background goitrogen exposure. The panel agreed that this assumption is partially valid. It is conceptually correct, but there is uncertainty whether the small data set adequately reflects goitrogen exposure in the general population. That said, the committee does not have an alternative approach to recommend. It considers the use of human data, even with uncertainties around these coexposures, far superior to alternatives such as relying on toxicology studies in rodents or other animal species and does not think that absence of explicit modeling for other goitrogens should inhibit the use of the existing model.

<u>Topic 3. Identification of Published Literature and Quantitative Relationship of Thyroid</u> Hormone Levels to Neurodevelopmental Outcomes

Charge Question 9a: Criteria to identify studies and adequacy of the search

There was panel agreement that the search criteria to identify studies through each of the three steps of the literature review were clearly described. There was concern, however, that limiting the search to literature published after 2000 may have resulted in the omission of potentially useful studies.

Charge Question 9b: Summary and characterization of the literature

No concerns were raised by the panel regarding the accuracy or characterization of the literature in Chapter 5.

Charge Question 10a: Assumptions, strengths and limitations of focusing on five studies and their associated neurodevelopmental endpoints

The five studies identified by EPA each provide data showing a statistically significant relationship between maternal fT4 and one or more endpoints relevant to neurodevelopment. These studies provide data from human subjects in a form suitable for determining quantitative relationships between maternal fT4 and the extent of neurodevelopmental impairment. These were identified as strengths of the collective studies during panel discussion. Limitations of the study set identified by the panel include the absence of studies of a U.S. population, limited informational value of one of the endpoints presented, and the small number of studies.

In order to expand and improve the information available for quantitative assessment of the relationship between maternal fT4 and neurodevelopmental outcomes, the panel recommends a re-evaluation of the selection of studies. There are two elements to this re-evaluation. One element is an attempt to identify additional studies with useful data. The second element is to evaluate more critically the strengths and weaknesses of the studies in order to better assess which may provide the most valuable information.

For the first element of this re-evaluation, the EPA should consider the following:

- 1) Inclusion of studies with a broader range of endpoints for adverse neurodevelopmental effects. For example, studies showing a relationship between thyroid hormone levels and autism and ADHD endpoints should be considered, as they are now realized to be associated with early insufficiencies of thyroid hormone.
- 2) Obtain raw data from categorical studies (Group 2) and use them to derive quantitative relationships if feasible. During the face-to-face meeting, the EPA was queried and indicated that they had not attempted to contact authors of categorical studies to request data.
- 3) Inclusion of studies with an association between thyroid hormone effects and neurodevelopmental outcomes that did not reach statistical significance. Quantitative

relationships could be derived by combining data from these studies with data from studies that found a statistically significant relationship. The panel acknowledges the difficulties with this approach, and that it could only be done for studies with the same endpoint(s) and similar design and study populations, and may require some normalization of data.

The second element is a critical assessment of the strengths and weaknesses of the studies used to derive quantitative relationships between maternal fT4 and neurodevelopment endpoints. During panel discussion of the five selected studies, a number of weaknesses in the individual studies were noted, such that some could be considered stronger than others. The report currently does not contain this type of assessment. Also, the report does not convey insight into what the various endpoints being measured represent, and therefore their informational value. The panel recommends that a critical assessment of the strengths and weaknesses of these studies, as well as any additional studies or analyses emerging from the first element (above) be added to the report. The results of this assessment could be used to identify which studies are sufficiently robust to use for Stage 2 modeling and which are not, or to provide a means to weight the value of information from individual studies.

Charge Question 10b: Sufficient number, quality, and robustness of the five studies for derivation of an MCLG

The re-evaluation of studies recommended in the response to Charge Question 10a will result in a set of candidate studies with a critical assessment of their strengths and weaknesses. From this assessment, the strongest studies should be apparent. The panel considers the robustness of the studies to be more important than the number of studies — a single study of sufficient robustness and quality would be sufficient for the derivation of an MCGL.

Charge Question 10c: Advice on reducing any identified limitations

The response to this charge question is largely covered in the response to Charge Question 10a. While only a limited number of studies may be used for the quantitative characterization, it would be beneficial to the credibility of the MCLG to characterize the strength of the overall data base of studies assessing the relationship between thyroid hormone levels and neurodevelopmental outcomes. Categorical studies (absent reanalysis of their data as described earlier) will not allow assessment of quantitative relationships, but can be valuable for assessing whether the relationship is consistently observed across studies including in US populations.

Charge Question 11a: Assumptions, strengths and limitations of the regression analysis to inform the relationship between thyroid hormone levels and neurodevelopmental outcomes

There is reason to expect that the relationship between a change in maternal fT4 levels and the corresponding change in neurodevelopmental outcomes will change within the full range of fT4 concentrations. Thus, the best choice for regression form (linear, log-linear quadratic) will depend upon a number of factors. The panel finds that the rationale for choice of regression form selected was not always clearly explained in the report, and recommends that the choices be re-visited keeping in mind the following considerations: 1) the choice should result in a satisfactory fit of the data; 2) the choice should make biological sense; and 3) the choice is

appropriate for the dose range being evaluated. For example, a linear or log-linear regression might be appropriate over a limited dose range, while a quadratic might be needed to fit a more complex relationship (e.g., a flattening of the curve or inverted U-shaped curve) over a wide range of maternal fT4 concentrations. One panel member suggested that fitting data to a Michaelis-Menten form would have a stronger biological basis and appropriate to consider.

Charge Question 11b: Additional data or analyses EPA could use to quantify the relationship between thyroid hormone levels and neurodevelopmental effects

The response to this charge question is covered in the response to Charge Question 10a.

Charge Question 11c: Whether there is a magnitude of change of fT4 below which the relationship between fT4 and neurodevelopmental effects should be used because it is too uncertain

There was agreement that there is no minimum fT4 change below which the relationship between fT4 and neurodevelopmental effects should not be used.

Charge Question 11d: Other studies that could be used to quantitatively characterize the relationship between fT4 and neurodevelopmental outcomes or inform uncertainty associated with the analysis presented

The response to this charge question is covered in the response to Charge Question 10a.

<u>Topic 4: Alternative Population-Based Approach and Comparison to the Two-Stage</u> <u>Approach Linking Thyroid Hormone Levels to Neurodevelopmental Outcomes</u>

Charge Question 12: Assumptions, strengths, and limitations associated with the population-based approach

The panel agreed that the population-based approach had the following strengths: 1) The central premise, that hypothyroxinemia is associated with adverse neurodevelopmental effects is supported by a large number of studies, including categorical studies; 2) This approach encompasses a variety of adverse neurodevelopmental outcomes, as indicated by these studies, rather than focusing on one or a limited number of adverse outcomes, as with the two-stage approach; and 3) This approach avoids all of the uncertainties associated with determining a quantitative relationship between a specific maternal fT4 level and the magnitude an adverse neurodevelopmental effect. The panel also agreed that this approach has the following limitations: 1) The endpoint (hypothyroxinemia) is not itself an adverse effect, but rather is a precursor effect. This may create challenges in explaining the basis for the MCLG to some audiences; and 2) A cut point for hypothyroxinemia has not been clearly established for other purposes, such as clinical practice. Further, it is possible that a definition of hypothyroxinemia that best meets the needs of clinical medicine is different from the definition used for regulatory purposes to provide protection from adverse effects of perchlorate. Although there could be sound reasons for different working definitions, this may lead to difficulty in communicating the population at risk, which is central to this approach.

Charge Question 13: Assumptions, strengths, and limitations of the derived fT4 distribution

The panel noted with concern that the model produces a counterintuitive result wherein the effect of perchlorate on individuals with higher percentile fT4 appears to be greater than individuals with lower percentile fT4. The expectation of the panel is that the effect would be the same at different percentiles fT4, or that a greater effect would occur with individuals that already have lower fT4 levels. As the EPA acknowledges, this result may be due to the assumption that maternal fT4 levels at different gestational ages are distributed lognormally. As discussed in response to Charge Question 3A, the panel recommends that the choice for this distribution be re-visited. EPA noted that the counterintuitive result may also be due to an artifact of the modeled relationship between iodine intake and free T4 levels, which showed a steeper slope at the higher percentiles of free T4.

Charge Question 14: Strengths and limitations of the two-stage model versus the alternative population-based approach

The panel agreed that strengths of the two-stage approach include explicit linkage between perchlorate exposure and a recognized adverse effect. Although the manner in which they are linked is highly technical, it is a concept that can be readily understood, facilitating risk communication related to the MCLG. The principal limitation of this approach is the small number of studies able to contribute data to the modeling and uncertainties associated with various modeling steps. The strengths and limitations of the alternative population-based model are described in the response to Charge Question 12.

Charge Question 15: Whether there are better strategies for estimating the potential impact of perchlorate exposure in early pregnancy on neurodevelopmental outcomes

The panel did not identify a better strategy for estimating the potential impact of perchlorate exposure on neurodevelopmental outcomes. The single study approach, as illustrated in Appendix C, is not recommended. The traditional MCLG approach of developing a perchlorate reference dose that includes uncertainty factors and combining it with assumed exposure levels to derive an MCLG was also discussed and rejected by the panel. In the panel's opinion, the BBDR approach makes the best use of available science.

1. INTRODUCTION

Perchlorate is a naturally occurring and manufactured chemical anion that consists of one chlorine atom bonded to four oxygen atoms (ClO₄-). Perchlorate is commonly used as an oxidizer in rocket propellants, munitions, fireworks, airbag initiators for vehicles, matches and signal flares. It is naturally occurring in some fertilizers. On February 11, 2011, the U.S. Environmental Protection Agency (EPA) determined that perchlorate meets the Safe Drinking Water Act (SDWA) criteria for regulation as a contaminant and is developing a National Primary Drinking Water Regulation (NPDWR) for perchlorate in accordance with the requirements under the SDWA. The Agency found that perchlorate may have an adverse effect on the health of persons and is known to occur in public drinking water systems with a frequency and at levels that present a public health concern. Since that time, EPA has been reviewing the best available scientific data on a range of issues related to perchlorate in drinking water including its health effects, occurrence, treatment technologies, analytical methods and the costs and benefits of potential standards. As one part of this process, Versar, Inc. (Versar), an EPA contractor, organized an independent peer review of EPA's "Draft Report: Proposed Approaches to Inform the Derivation of a Maximum Contaminant Level Goal for Perchlorate in Drinking Water" (MCLG Approaches Report).

1.1 Information on EPA's Revised Biologically Based Dose-Response (BBDR) Model

As a part of the NPDWR development process for perchlorate, in accordance with the requirements of the Safe Drinking Water Act, in 2012, EPA requested comment from EPA's Science Advisory Board (SAB) prior to proposing an MCLG and a NPDWR for perchlorate. EPA sought guidance on how best to consider and interpret life stage information, epidemiologic and biomonitoring data, physiologically-based pharmacokinetic analyses and the totality of perchlorate health related information to derive a perchlorate MCLG.

In 2013, the SAB recommended that, ". . . EPA derive a perchlorate MCLG that addresses sensitive life stages through physiologically-based pharmacokinetic/pharmacodynamic (PBPK/PD) modeling based upon its mode of action rather than the default MCLG approach using the reference dose and specific chemical exposure parameters" (Advice on Approaches to Derive a Maximum Contaminant Level Goal for Perchlorate, EPA-SAB-13-004).

Based on the SAB's recommendations, EPA, with contributions from Food and Drug Administration scientists, developed a biologically based dose response (BBDR) (also known as a PBPK/PD) model, to predict the effects of perchlorate on serum thyroid hormone concentrations in pregnant and lactating women exposed to perchlorate in drinking water and in infants exposed via ingestion of perchlorate in formula or breast milk.

On January 10 and 11, 2017, Versar, Inc. conducted an independent, scientific peer review of EPA's draft BBDR model and draft model report. The purpose of the peer review was to provide a documented, independent, and critical review of the draft BBDR model and draft model report and to identify any necessary improvements to the model prior to being finalized. The final peer review report entitled, "External Peer Review for EPA's Draft Biologically Based Dose-Response (BBDR) Model and Draft BBDR Model Report for Perchlorate in Drinking Water" is

available through the EPA docket at https://www.regulations.gov/docket?D=EPA-HQ-OW-2016-0439.

In developing the draft MCLG Approaches Report, EPA revised the BBDR model to address those peer review recommendations that had the greatest influence on the scientific rigor and robustness of the model. Those changes are described in the draft MCLG Approaches Report.

1.2 Information on EPA's Draft Approaches To Inform the Derivation of a Perchlorate MCLG

The SAB also recommended that EPA, "utilize a mode of action (MOA) framework for developing the MCLG that links the steps in the proposed mechanism leading from perchlorate exposure through iodide uptake inhibition to thyroid hormone changes and finally neurodevelopmental impacts."

EPA used the modeled thyroid hormone levels to predict potential adverse health effects based on published epidemiology data demonstrating a relationship between changes in thyroid hormone levels and neurodevelopmental effects. This approach involved a systematic review of the literature connecting altered thyroid hormone levels to neurodevelopmental outcomes for women in early pregnancy. EPA focused on studies that provided a quantitative description of the relationship between free thyroxine and neurodevelopment in infants and children (e.g., intelligence quotient, verbal and problem solving skills and motor coordination).

In the draft MCLG Approaches Report, EPA presented an array of approaches to inform selection of an MCLG for perchlorate for expert peer review. EPA identified five studies from which it derived statistical relationships that result from changes in thyroid hormone levels, thus utilizing the MOA framework linking perchlorate exposure to neurodevelopmental impacts. Using the revised BBDR model output, all five studies assess the relationship between thyroid hormone levels in women in early pregnancy and various neurodevelopmental effects on children at various ages. Two studies assess the relationship on the IQ of children 5 to 10 years of age, two other studies assess the relationship on Bayley Scales of Infant Development of children 1 to 2 years of age, and a fifth study assesses the relationship on reaction time of children 5 to 6 years of age. An additional approach uses the revised BBDR model output to predict the percent change in the population of hypothyroxinemic (or the low-end of normal thyroid hormone levels) in pregnant women due to perchlorate exposure.

1.3 Peer Review Process

The peer review of the MCLG Approaches Report is the second peer review (Panel 2) the Agency undertook to determine the appropriate scientific approach for understanding the adverse health impacts of perchlorate in drinking water. The first peer review (Panel 1) was held on January 10 and 11, 2017, and focused on the BBDR model and model report. The reviewer selection process for Panel 2 was a continuation of the original perchlorate peer review efforts, as the Agency previously intended to have only one panel to cover both the BBDR model and the MCLG Approaches Report. Thus, reviewers were identified to cover expertise needed for both documents during the Panel 1 reviewer selection process.

The reviewer identification process was initiated by EPA with a request for nominations of peer reviewers in a March 1, 2016 Federal Register Notice (FRN; 81 FR 10617). Members of the public were able to nominate scientific experts with knowledge and experience in one or more of the following four areas: (1) PBPK, PBPK/PD and/or BBDR modeling, (2) fetal and neonatal thyroid endocrinology (clinical and experimental), (3) iodide homeostasis, and (4) perchlorate toxicology and mode of action or adverse outcome pathway. On June 3, 2016, EPA announced in a second FRN (81 FR 35760) that they expanded the scope of the peer review to include the review of the application of the BBDR model to develop a perchlorate MCLG. With this change in scope, the notice requested additional nominations for peer reviewers with knowledge and experience in a fifth area: human health risk assessment with an understanding of thyroid function (preferably in the sensitive life stages of interest), the importance of maternal thyroid hormone homeostasis in each stage of gestation, hypothyroxinemia, neurodevelopmental assessment indices for young children including the Bayley's Scale, the toxicity of perchlorate, epidemiological assessment techniques, and statistics.

Versar also conducted independent searches for qualified scientific experts to augment the list of publically-nominated candidates. Searches were conducted in 2016 prior to the first panel (concurrent with the public nomination periods) and in 2017 prior to the second panel. Versar considered and screened all nominees and Versar-identified candidates to confirm their interest in and availability for conducting the review, qualifications, lack of conflict of interest, and impartiality.

An interim list of 12 candidates for the second panel on the draft MCLG Approaches Report was published on September 15, 2017 in the Federal Register (82 FR 43361), which included the names, professional affiliations, expertise, education, and professional experience of the individuals. The FRN provided a 21-day period for the public to submit relevant information or documentation on the proposed list of candidates that Versar should consider during the evaluation process of selecting the final reviewers. After carefully considering all comments received, Versar selected the eight experts for who, collectively, provided the expertise areas required by EPA's selection criteria, and, to the extent feasible, best provided a balance of perspectives. EPA announced the reviewer names and affiliations in a November 28, 2017 Federal Register Notice (82 FR 56235). Biographical sketches for each of the selected reviewers are included in Appendix A.

PEER REVIEWERS

Hugh A. Barton, Ph.D. Pfizer, Inc.

Nancy Carrasco, M.D., M.S. Yale School of Medicine

Jonathan Chevrier, Ph.D.
McGill University Faculty of Medicine

Claude Emond, Ph.D.

University of Montreal

Dale Hattis, Ph.D.

Clark University

Angela M. Leung, M.D., M.Sc.

UCLA David Geffen School of Medicine

Stephen M. Roberts, Ph.D.

University of Florida

Joanne F. Rovet, Ph.D.

The Hospital for Sick Children (Toronto), Emeritus

Following selection Versar provided each of the peer reviewers the review materials, which included EPA's "Draft Report: Proposed Approaches to Inform the Derivation of a Maximum Contaminant Level Goal for Perchlorate in Drinking Water" (MCLG Approaches Report) and the revised BBDR model. Reviewers were instructed to evaluate the model and model report, provide general comments and overall impressions of the scientific merit of the model and model report, respond to 15 charge questions, and provide other specific comments that they felt would improve the information in the model and model report. In addition, the reviewers were provided with public comments on the revised model and MCLG Approaches Report (in their entirety) submitted during the public comment period for their consideration.

On January 29 and 30, 2018, Versar convened a public peer review meeting in Arlington, Virginia. This meeting was held to discuss the scientific basis supporting EPA's draft MCLG Approaches Report and revised BBDR Model for perchlorate in drinking water, and to provide members of the public with an opportunity to observe the peer reviewer deliberations. The meeting followed the public comment period and the pre-meeting written peer review period, during which the eight selected peer reviewers evaluated the peer review materials and provided preliminary comments in response to the 15 charge questions.

Versar managed the pre-meeting registration period, which allowed members of the public to register to attend the meeting in person or remotely via teleconference and/or webinar. Members of the public were able to register by telephone, email, or facsimile. In advance of the meeting, Versar provided all registered attendees with pre-meeting handouts, which included the agenda (Appendix B) and logistics information. Approximately 50 public observers attended the peer review meeting in person and 48 observers attended the meeting via teleconference and/or webinar. A list of pre-registered meeting attendees is provided in Appendix C.

Peer Review Meeting – Day One

On the first day of the meeting, Versar began by providing information on the overall peer review process and introducing the peer reviewers. EPA's introduction to the meeting was made by Mr. Eric Burneson, the Director of Standards and Risk Management Division in EPA's Office

of Water. Next, two technical presentations were made by EPA. Dr. Paul Schlosser, with the EPA National Center for Environmental Assessment Office, provided a summary of EPA's BBDR modeling effort. Dr. Ahmed Hafez, with the EPA Office of Water's Standards and Risk Management Division, provided a summary of the proposed approaches to inform the derivation of an MCLG for perchlorate in drinking water. A brief observer comment session followed these technical presentations, during which the following five individuals presented oral statements:

- Richard Pleus, Intertox, Inc.
- Lisa Corey, Intertox, Inc.
- Larry Leroy Ladd, citizen of City of Rancho Cordova, California
- Kevin M. Morley, American Water Works Association
- Jennifer Sass, National Resources Defense Council

Following the observer comment period, the peer reviewers began their discussions on the revised BBDR model and draft MCLG Approaches Report, which centered on individual responses to EPA's first ten charge questions. The discussion was moderated by the Chair, Dr. Stephen Roberts.

Peer Review Meeting - Day Two

The second day of the meeting began with brief opening remarks from Versar, followed by a welcome from Ms. Lisa Christ, Chief of the Targeting and Analysis Branch in EPA's Office of Water. The peer reviewers then continued their discussion of the charge questions, beginning where they had left off on Day One (Charge Question 10).

Preparation of Post-Meeting Comments

Following the public peer review meeting, peer reviewers were given additional time to revise and complete their individual pre-meeting written reviews. These final written comments are contained in Sections 2 through 7 of this report. EPA will consider the written peer review comments, as well as comments submitted to the EPA docket by members of the public, in determining the appropriate scientific approach for understanding the adverse health impacts of perchlorate in drinking water and taking the next appropriate steps under the Safe Drinking Water Act.

2. CHARGE TO REVIEWERS

Introduction

EPA is developing approaches to inform the derivation of a Maximum Contaminant Level Goal (MCLG) for perchlorate. In January 2017, EPA's contractor (Versar, Inc.) conducted an independent, external, scientific peer review of the draft biologically-based dose-response (BBDR; also known as a PBPK/PD) model and report titled: BBDR Models for the Effect of Perchlorate on Thyroid Hormones in the Infant, Breast Feeding Mother, Pregnant Mother, and Fetus: Model Development, Revision, and Preliminary Dose-Response Analyses. The model predicts the relationship between perchlorate exposure and thyroid hormone levels in sensitive life stages and has been revised based on peer reviewer recommendations.

The purpose of this review is to seek guidance from expert peer reviewers on the scientific assessment titled: *Draft Report: Proposed Approaches to Inform the Derivation of a Maximum Contaminant Level Goal for Perchlorate in Drinking Water* (e.g., draft MCLG Approaches Report), which links the revised perchlorate BBDR model predictions to neurodevelopmental effects, to inform decision-making for perchlorate under the Safe Drinking Water Act. The outcome of this peer review is not the derivation of an MCLG; rather, it is to solicit expert comment on the proposed approaches that might be used to inform future decisions on the derivation of an MCLG.

MCLGs are non-enforceable, health-based goals that EPA sets for each regulated drinking water contaminant. In accordance with the Safe Drinking Water Act (SDWA), they are set at a level at which no known or anticipated adverse human health effect occurs and to allow for an adequate margin of safety. MCLGs consider only public health, and not limits of analytical measurement and treatment technology effectiveness. The SDWA requires that EPA establish the enforceable Maximum Contaminant Level (MCL) as close as feasible to the MCLG taking costs and benefits into consideration.

Peer Review History

In 2012, as a part of the national primary drinking water regulation development process for perchlorate and in accordance with the requirements of the SDWA, EPA sought recommendations from EPA's Science Advisory Board (SAB) on approaches to inform the derivation of a perchlorate MCLG.

In 2013, the SAB recommended the following:

- derive a perchlorate MCLG that addresses sensitive life stages through physiologically-based pharmacokinetic/pharmacodynamic modeling (PBPK);
- expand the modeling approach to account for thyroid hormone perturbations and potential adverse neurodevelopmental outcomes from perchlorate exposure;
- utilize a mode of action framework for developing the MCLG that links the steps in the proposed mechanism leading from perchlorate exposure through iodide uptake inhibition to thyroid hormone changes and finally neurodevelopmental impacts; and
- extend the [BBDR] model expeditiously to...provide a key tool for linking early events with subsequent events as reported in the scientific and clinical literature on iodide deficiency, changes in thyroid hormone levels, and their relationship to neurodevelopmental outcomes during sensitive early life stages.

The SAB stated that this data-driven approach represents a more rigorous way to address differences in biology and exposure between adults and sensitive life stages than is possible with the default approach for deriving an MCLG, and that EPA should also consider available data on potential adverse health effects (neurodevelopmental outcomes) due to thyroid hormone level perturbations regardless of the cause of those perturbations. See <u>Advice on Approaches to Derive</u> a Maximum Contaminant Level Goal for Perchlorate, EPA-SAB-13-004.

Based on the SAB's recommendations, EPA, with contributions from the Food and Drug Administration, developed a BBDR model to predict the effect of perchlorate on the thyroid gland in formula-fed and breast-fed infants, and in lactating women. This draft model was integrated with a previously published model that similarly predicted the effects of perchlorate on serum thyroid hormone concentrations in the third trimester pregnant woman and her fetus. The model was subjected to external peer review in January 2017. The final peer review report titled *External Peer Review for EPA's Draft Biologically Based Dose-Response (BBDR) Model and Draft BBDR Model Report for Perchlorate in Drinking Water* is available through the docket at https://www.regulations.gov/docket?D=EPA-HQ-OW-2016-0439

Revisions to the BBDR Model Following the January 2017 Peer Review

EPA considered all of the peer reviewers' recommendations from the January 2017 peer review and focused on those that were anticipated to be most important for increasing the scientific rigor of the model and modeling results. These revisions are summarized in Chapter 3 of the draft MCLG Approaches Report; additional detail is available in Appendix A. Model revisions focused on the following key recommendations:

- extending the model to early pregnancy;
- incorporating biological feedback control of hormone production via TSH signaling, such that the model can describe lower levels of iodide nutrition;
- calibrating the model and evaluating its behavior for upper and lower percentiles of the population, as well as the population median; and
- conducting an uncertainty analysis for key parameters.

The revised BBDR model does not explicitly address consideration of other goitrogens. Previous peer reviewers (2017) were mixed on their recommendations regarding the issue of consideration of other goitrogens. A recent review of thiocyanate pharmacokinetics and modes of action indicates that an attempt to address other goitrogens in the model would involve significant uncertainty (Willemin & Lumen, 2017). However, it is expected that the model predictions may, in fact, incorporate the effect of perchlorate along with exposure to other goitrogens because the model predictions for zero perchlorate exposure are calibrated to National Health and Nutrition Examination Survey (NHANES) data, which are from a population with an exposure distribution to other goitrogens that is assumed to be independent of perchlorate.

EPA's Approaches for Informing the Derivation of an MCLG

EPA has developed a two-stage approach linking the revised BBDR model results with quantitative information on neurodevelopmental outcomes from epidemiological studies. EPA has also developed an alternative population-based approach that uses the revised BBDR model to evaluate a shift in the population of pregnant women who could be hypothyroxinemic.

The first stage of the two-stage approach is the development of the revised BBDR model that describes thyroidal hormone production in women of childbearing age with low/adequate iodide

intake, and predicts the relationship between perchlorate exposure and changes in thyroid hormone levels in early pregnancy. The available data for the second stage of the analysis comes from epidemiological studies that evaluated maternal thyroid hormone levels in early pregnancy and neurodevelopmental outcomes (these are not studies evaluating perchlorate exposure). Based on the recommendations of previous peer review panels, EPA assumed that changes in thyroid hormone levels would be expected to lead to neurodevelopmental outcomes. For this reason, EPA did not conduct a complete, systematic review of the body of literature on this topic. However, EPA conducted a focused review of the published literature and identified 29 epidemiological studies that examined thyroid hormone levels and neurodevelopmental outcomes. Of these 29 studies, 14 provide categorical data that assist in understanding the implications of altered thyroid hormones, and 15 provide more detailed dose-response characterizations via regression analyses to inform the relationship between low thyroid hormone levels and neurodevelopmental effects in offspring.

EPA focused on the latter set of 15 studies due to their more robust dose-response analyses, which included studies that found statistically significant changes and studies that did not find a statistically significant correlation. Among these studies, the number of subjects ranged from 22 to 3,839. In many of these studies the general outcomes, though not statistically significant, showed a positive relationship that was consistent with the studies used for quantitative analyses. In some instances, the studies had results that were negative or inconsistent with the studies that were used for the quantitative analyses. EPA presents and characterizes all of these studies in Chapter 5 of the report.

Five studies in this group of 15 were identified (Pop et al., 1999; 2003; Finken et al., 2013; Korevaar et al., 2016; and Vermiglio et al., 2004) that included data that were used to quantitatively describe the relationship between thyroid hormone levels in early pregnancy (the focus of the analysis) and changes in neurodevelopment in offspring. Neurodevelopmental outcomes associated with these studies included assessment of Bayley Scales of Infant Development, Weschler Intelligence Scales for Children, a Dutch non-verbal intelligence test (the Snijders-Oomen Niet-Verbale Intelligentie Test) and Standard Deviation of Reaction Time

Using the output from the revised BBDR model (stage 1 of the analysis) and the quantitative relationships between thyroid hormone levels and neurodevelopmental effects from the published epidemiological studies (stage 2 of the analysis), EPA characterized the relationship between perchlorate exposure on fT4 levels in pregnant mothers during early gestation and the potential for changes in neurodevelopmental outcomes in their offspring.

EPA's alternative population-based approach estimates the shift in the population of hypothyroxinemic, pregnant women that would result from perchlorate exposure. EPA used the BBDR model predictions to estimate the proportion of hypothyroxinemic pregnant mothers in the population, assuming a distribution of fT4 levels with a consistent iodide intake.

Charge Questions

Topic #1: General Questions

- 1. Please comment on the appropriateness of focusing the current evaluation on perchlorate's potential impact on the fetuses of hypothyroxinemic pregnant women during early gestation for the purposes of informing a perchlorate MCLG.
- 2. Please identify any additional peer-reviewed studies that could inform the BBDR modeling or the quantitative relationship of thyroid hormone levels to neurodevelopmental outcomes. If an alternative study data set would be more appropriate, please outline how such data might be used.

Topic #2: BBDR Modeling to Predict Changes in Thyroid Hormone Levels in Early Pregnancy

The revised BBDR model seeks to predict the pharmacokinetics and pharmacodynamics of iodide and perchlorate, as well as the thyroid hormones T3 and T4 and TSH, in non-pregnant and pregnant women, including those with low iodide intake, and changes in thyroid hormone levels.

- 3. Please comment on the assumptions, strengths and limitations of methods and parameters by trimester for:
 - a. determining the quantitative relationships between oral intake and serum levels of perchlorate during pregnancy under continuous exposure assumptions, and
 - b. estimating statistical distributions of specific biochemical parameters that determine serum perchlorate concentrations, urine clearance of iodide and perchlorate, and thyroid iodide uptake for purposes of estimating the effect of environmental levels of perchlorate on maternal fT4 concentrations.
- 4. Please comment on the assumptions, strengths and limitations of the uncertainty analyses of the parameters, particularly with regard to availability of data supporting parameter assumptions.
- 5. Please comment on the utility of the BBDR model for predicting variability in fT4 levels in the population (e.g., percentiles for different thyroid hormone levels) at varying levels of iodide intake.
- 6. Please comment on the robustness, precision and sensitivity of the model, and how these factors affect the model's ability to predict changes in fT4 at low perchlorate doses. Consider whether a perchlorate dose range exists for which the modeling predictions would be highly uncertain.
- 7. The revised BBDR model incorporates a TSH feedback loop defined by an equation from Hadlow et al. (2013) (J Clin Endocrinol Metab, 98(7): 2936-2943), with an adjustment factor to match specific data sets or population percentiles, to describe the relationship between fT4 and TSH.

- a. Please comment on the assumptions, strengths and limitations of this approach to incorporate a TSH feedback loop into the BBDR model.
- b. Noting the reliance on the Hadlow et al. (2013) study, please comment on whether there are other studies that should be considered and describe how they would improve the analysis.
- c. Please comment on the approach for characterizing inter-individual variability in relevant populations from which the epidemiological data were obtained.
- 8. Since the observational thyroid hormone data that are used to calibrate the model derive from populations exposed to goitrogens other than perchlorate, EPA has made an assumption that the model parameters may implicitly account for exposures to these other goitrogens. As such, the exposure to perchlorate is assumed to be effectively added to this background goitrogen exposure as discussed in Chapter 3.5 of the report.
 - a. Please comment on the validity of this assumption and the extent of uncertainty associated with this assumption.

Topic #3: Identification of Published Literature and Quantitative Relationship of Thyroid Hormone Levels to Neurodevelopmental Outcomes

- 9. EPA conducted a three-step literature review, which identified 15 studies with information that could inform the quantitative relationship between thyroid hormone levels and neurodevelopmental outcomes.
 - a. Please comment on whether EPA has clearly identified the criteria to identify studies through each of the three steps of the literature review, and the adequacy of the strategy for conducting the literature search. Are these criteria scientifically supportable, and did EPA apply them properly?
 - b. Please also comment on the summary and characterization of the literature in Chapter 5 of the MCLG Approaches Report and identify any inaccuracies or mischaracterization of the studies.
- 10. EPA focused on five studies that evaluated the relationship of maternal fT4 and several neurodevelopmental endpoints (IQ, MDI, PDI and reaction time) based on the measurement of fT4 during early pregnancy at weeks 12, 13 and 16.
 - a. Please comment on the assumptions, strengths and limitations of focusing on the five studies and associated neurodevelopmental end points to inform an MCLG, including but not limited to study design, evaluation of neurological endpoints, sample size, iodide nutrition status, potential confounders such as smoking, and study population.
 - b. Please comment on whether the chosen studies are sufficient in number, quality, and robustness for the purpose of informing the derivation of an MCLG.
 - c. Please provide advice on reducing any identified limitations.

- 11. EPA used regression analyses to predict the magnitude of change in each of the neurodevelopmental endpoints given a change in fT4 as a result of increased perchlorate exposure at different iodide intakes.
 - a. Please comment on the assumptions, strengths, and limitations of using the regression analyses to inform the relationship between thyroid hormone levels and neurodevelopmental outcomes. Please also comment on the various functional forms of the regression equations (e.g. linear, log-linear, quadratic) in each of the relationships.
 - b. Please identify additional data or analyses EPA could use to quantify the relationship between thyroid hormone levels and neurodevelopmental effects, including how this information would be expected to improve the analysis.
 - c. Please comment on whether there is a magnitude of change in fT4 below which the relationship between fT4 and neurodevelopmental effects should not be used because it is too uncertain.
 - d. Please comment on whether other studies that were identified in the literature search (e.g., studies that found categorical relationships between fT4 and neurodevelopmental outcomes, studies that found effects but lacked statistical significance, studies that did not find an effect) could be utilized to quantitatively characterize the relationship between fT4 and neurodevelopmental outcomes or inform uncertainty associated with the analysis presented.

Topic #4: Alternative Population-Based Approach and Comparison to the Two-Stage Approach Linking Thyroid Hormone Levels to Neurodevelopmental Outcomes

- 12. Please comment on the assumptions, strengths and limitations associated with the population-based approach that is focused on a shift in the proportion of the population that could be considered hypothyroxinemic.
- 13. Hypothyroxinemia is the condition of having an abnormally low level of T4 in the blood and TSH is in the normal range, and in diagnosing this condition the threshold for "abnormally low" is often selected to be the 2.5th, 5th or 10th percentile of the population fT4 distribution. Because the BBDR model can be calibrated to any given percentile, but does not predict the distribution of fT4 levels, it was necessary to derive a fT4 distribution to identify a hypothyroxinemic threshold. EPA assumed a lognormal distribution with a Geometric Standard Deviation based on 2 to 3 studies depending on the gestational week. There is uncertainty regarding the true fT4 levels at various percentiles in the distribution around the median output from the BBDR model. For example, some of the analyses show larger unit changes with increasing percentiles of fT4 in most analyses (See tables 24, 30, 31, 32, 33 and Section 6.5.6 of the MCLG Approaches Report). Please comment on the assumptions, strengths and limitations of the derived fT4 distribution for the purposes of this analysis.
- 14. Please comment on the strengths and limitations of the two-stage approach versus the alternative population-based approach to inform the derivation of an MCLG.

15. EPA has developed a two-stage approach linking the revised BBDR model results with quantitative information on neurodevelopmental outcomes from epidemiological studies. Please comment on the utility of the this two-stage approach for predicting potential impact of perchlorate exposure in early pregnancy on neurodevelopmental outcomes in the population at varying levels of iodide intake. Please comment on whether there are better strategies for estimating the potential impact of perchlorate exposure in early pregnancy on neurodevelopmental outcomes that are likely to be more scientifically defensible than the approaches presented (e.g. Appendix C estimates IQ impact directly from perchlorate exposure using Steinmaus et al. and Korevaar et al., or potentially some alternative studies). If an alternative approach would be more appropriate, please outline specifically how the approach might be developed given the current available state-of-the-science and data.

3. GENERAL IMPRESSIONS

Hugh A. Barton, Ph.D.

The draft document and appendices are generally well written and present a sound approach to address the issue of assessing the potential neurodevelopmental impacts of perchlorate exposure during early pregnancy as a sensitive developmental window. The approach is consistent with the recommendations of the 2012-2013 EPA SAB Committee report. That report recommended elaborating the PBPK/PD model to include hormonal changes that would arise in response to perchlorate inhibition of iodide transport, the original endpoint for the model discussed in the 2012-2013 EPA SAB Committee report. It was further recommended that the predicted hormonal changes be linked with dose-response information describing the relationship between altered thyroid hormone concentrations and effects on neurodevelopment.

The current document describes just such an approach, modeling iodine and perchlorate pharmacokinetics, their competitive interaction at the iodide transporter, and the consequences for circulating maternal thyroid hormone concentrations including feedback via TSH and pregnancy induced changes due to hCG. This PBPK/PD model, tested against available information in the literature, is then used to predict impacts of perchlorate on thyroid hormone levels. These levels are then related to expected changes in neurodevelopment based upon published literature describing these outcomes in relation to thyroid hormone levels.

This approach, while it has uncertainties that are described in the report, avoids the major uncertainties of animal to human extrapolation if toxicological studies were proposed as the basis for the MCLG and those noted briefly in a later paragraph from using a simpler approach adjusting the RfD for body weight and drinking water consumption at different life stages. The modeling approach proposed also allows assessment of potential effects of perchlorate in a sensitive window of development during which it now might be considered unethical to carry out a controlled clinical study. This contrasts with the studies of inhibition of iodide uptake evaluated in healthy male and female volunteers, one of the important sources of data for this modeling effort along with epidemiological and observational human studies.

That said, this is a model of substantial complexity due to the pregnancy related changes in iodine and perchlorate pharmacokinetics and in the pharmacodynamics processes regulating thyroid hormone levels. Reading the documents, it is not easy to obtain a clear and thorough understanding of the model's ability to predict median population behavior as well as predict behaviors in the hypothyroxinemic tails of the distribution for pregnant women. Appendix A is much more technically demanding and requires expertise in the relevant areas to understand much of the information. Section 1.3, describing the probabilistic analysis, was extremely difficult for this reviewer to read as this was not my area of expertise.

It is worth noting that while public reviewers are appropriately concerned about the uncertainties and potential limitations of this complex modeling approach, the range of potential acceptable drinking water levels (Health Reference Levels) derived using simple body weight and water consumption adjustments for different life stages is reported to be $1-47~\mu g/mL$ (p 1-4). It is easy to criticize any single approach and difficult to assess the degree of uncertainty across approaches. The simpler default type approach, for example, suggests bottle-fed infants need the lowest concentrations while pregnant and non-pregnant women are protected by similar water

concentrations because they have similar body weights and drinking water consumption with no consideration of changing iodide needs due to pregnancy. EPA is long overdue in moving forward with public health protections for perchlorate, but may benefit from comparisons among these approaches as it does develop an MCLG.

Nancy Carrasco, M.D., M.S.

Perchlorate contamination of drinking water in the United States is a serious problem because of the deleterious health effects of perchlorate on thyroid physiology. The primary function of the thyroid gland is to biosynthesize and release the thyroid hormones (T₃ and T₄), of which iodine is an essential constituent. The thyroid hormones are master regulators of intermediary metabolism in virtually all tissues throughout life and play a critical role in fetal and early life—specifically, in the development and maturation of the central nervous system, skeletal system, and the lungs. Insufficient amounts of thyroid hormones in the early stages of development lead to mental retardation and stunted growth.

The first step in the biosynthesis of the thyroid hormones is the active transport of iodide (I⁻) across the plasma membrane of the thyroid follicular cells. This process is mediated by a specialized plasma membrane transport protein, the Na⁺/I⁻ symporter (NIS), which couples the inward "downhill" translocation of Na⁺ down its electrochemical gradient to the inward "uphill" transport of I against its electrochemical gradient. The central consideration motivating the draft report and the entire effort by the EPA to protect the population from perchlorate contamination is that perchlorate interferes with thyroid function by acting as a competitive inhibitor of NIS, thus preventing I, to one or another extent, from reaching the thyroid. Crucially, perchlorate is not only a blocking inhibitor: it is actually a NIS substrate. NIS has a higher affinity for perchlorate than for I⁻. It is worth noting that the revised NIS affinity constant for perchlorate reported by Schlosser is exactly the same as that reported by Van Sande et al. (2013), a paper that should be cited. Tonacchera et al. (2004) reported that the affinity of NIS for perchlorate is 30 times its affinity for iodide. Therefore, in the presence of substantial concentrations of perchlorate in the plasma, NIS will preferentially transport perchlorate rather than I⁻ into the thyroid, thus decreasing thyroid hormone biosynthesis. In short, NIS is the key molecule at the center of this draft report.

I am a trained physician, a biomedical scientist, and a member of the National Academy of Sciences. My main area of expertise is transport across biological membranes. In 1996, my group was the first to clone the cDNA coding for NIS [Dai et al. (1996) *Nature*], a transporter we have been investigating at the molecular level in great detail for 22 years. We have published over 100 original peer-reviewed articles on NIS and topics related to transport across biological membranes in leading international journals, and have remained at the forefront of NIS research worldwide. We have characterized NIS extensively, elucidated many of its mechanistic and structure/function properties, and intensively studied its regulation and its medical applications, including that NIS is expressed in the lactating breast [Tazebay *et al.* (2000) *Nature Medicine*]. Furthermore, we were the first group to report that NIS actively transports perchlorate, and that it transports it with a stoichiometry (1 sodium : 1 perchlorate) different from the 2 sodiums : 1 anion stoichiometry with which it transports iodide [Dohan et al. (2009) *PNAS*, Paroder-Belenitsky *et al.* (2011) *PNAS*]. My impressions, which are informed by these qualifications, are as follows.

Overall, the report was carefully prepared, and it makes significant progress towards the goal of informing the EPA in its effort to derive a maximum contaminant level goal (MCLG) for perchlorate in drinking water. I sincerely commend the authors for what they have accomplished. For example, the report successfully summarizes the available papers on the effect of maternal hypothyroxinemia on the progeny. However, the report, especially in its sections that primarily deal with NIS and the effect of perchlorate on NIS, suffers from the following significant shortcomings: 1. the information presented is sometimes not accurate; 2. the presentation of both concepts and data is sometimes unclear; 3. numerous statements are made without being substantiated by proper references or, sometimes, by any references at all; 4. in many cases, where references are provided, these references are not the most relevant or the most appropriate; and 5. there is a general tendency to use references without regard to their true scientific value; for example, some of the articles cited present conclusions that were reached using outdated techniques that have now been shown to be invalid, and other articles cited are reviews rather than primary research papers, so the actual evidence for the relevant statements is missing altogether. Specific examples of these problems, drawn from throughout the text, are given below (under III. Specific Observations). Finally, as a result of these shortcomings, not all the conclusions reached in the report are sound. To give but one example, I am not aware of any evidence of NIS-mediated I transport activity in the skin or in erythrocytes, but both of these purported transport processes are nevertheless mentioned in the report as if they had been conclusively established to exist. My impression is that, although the authors of the report made a serious effort to provide evidence from the scientific literature to support their statements, they had no actual longstanding familiarity with the relevant literature on NIS. As a result, several key and seminal original research papers directly germane to the report were not mentioned, while papers with little bearing on the subject at hand or reporting on experiments carried out using outdated or discredited approaches were included.

Jonathan Chevrier, Ph.D.

I commend EPA for engaging in such a complex and ground-breaking enterprise in developing this two-stage BBDR model. The analysis and report were carefully and thoughtfully put together. The idea of using data from physiological parameters combined with epidemiological data in the development of a MCLG is certainly conceptually interesting and would be expected to be of greater value than using the fraction of a no-observed adverse effect level (NOAEL), as is commonly the case. However, this report demonstrates the difficulty of developing such models in a context in which much uncertainty remains. While there is convincing evidence that perchlorate affects circulating fT4 levels and that low fT4 during early pregnancy is associated with impaired neurodevelopment, the parameters underlying these effects are uncertain. Without being an expert in BBDR modeling, my impression was that the model was well thought through and the decisions that were made were well-supported. However, one question remained, which is whether uncertainty in fT4 prediction for each perchlorate exposure level had been quantified. My understanding is that Monte-Carlo types of analyses are generally run on such models to evaluate this uncertainly and I would have expected this to be carried over to the analysis of effects on neurodevelopment but this appeared to be missing. It is also unclear to me as to how the model can be validated. This said, my main concern is that the model predicts larger effects among women with higher fT4 levels than those with low fT4. This goes against what would be expected (effects should be stronger at the lower end of fT4), which suggests that issues remain with the BBDR model. My understanding is that this surprising result could be due to the fact

that fT4 was assumed to be log-normally distributed. Although the distribution of fT4 could presumably be log-normal among first-trimester pregnant women, not all studies reviewed by EPA reported log-normal distributions. In addition, these studies used immunoassays to measure fT4, some of which have been shown to be affected by the concentration of T4-bound proteins. Since the concentration of T4-bound protein changes as pregnancy progresses, fT4 measures from these studies may have been biased. It is unclear to me whether this may explain the skewed distribution of fT4 reported by some studies but this does question unexpected findings. It seems to me that one way or another the BBDR model needs to be adjusted so that its prediction agrees with current knowledge; and it would be useful to see results of the two-stage approach if a normal distribution of fT4 was assumed. Note also that I wonder if the method used to "average" the geometric standard deviations was correct (see comments below). EPA admitted that the modeled relation between free T4 and iodine intake (as shown in Figure A-54) may also explain the finding of a weaker effect of perchlorate at lower percentiles of free T4. This appears to be due to the fact that an intercept of zero was forced for all percentiles, thereby forcing slopes at the higher percentile to be steeper than those at lower percentiles. I would recommend against this type of extrapolation beyond the data. Finally, the lack of usable epidemiologic data that is similar enough that it could be meta-analyzed and the decision to rely solely on studies that generated statistically significant result limit the applicability of the twostage approach. My overall impression is that the approach has merit but I wonder if the necessary data is available to apply it to this question. I am also unclear as to how the data would ultimately be used to derive a MCLG. Given the inherent limitations of observational data and uncertainty of the BBDR model, I think that it is important that EPA consider using an uncertainty factor to derive the MCLG. This said, I want to make clear that, despite its limitation, I believe that the overall approach has ample merit and is a step in the right direction that ultimately should have a more solid scientific basis than the current approach based on NOAELs derived from animal studies.

Claude Emond, Ph.D.

Here, the goal of this work was to predict the concentration of perchlorate that will induce a significant reduction of the fT4, causing neurodevelopment issue for fetuses during development. Hypothyroxinemia in pregnancy is defined as the presence of a free thyroxine (FT4) value below the 2.5th percentile with the thyrotropin (TSH) level within the reference range. Here, EPA develops a BBDR model trying to relate the exposure of perchlorate to hypothyroxinemia during pregnancy. When we review the document, it is clear to me that several parameters are very variable and not unique. Only trying to understand the relation between TSH and fT4 from the literature is so very different across-study that when plotted on a graph, the conclusion of this relation is difficult to make. It is probably based on the reserves of T4. Other physiologic causes, other than perchlorate, can also be implicated as exacerbating blood fT4 concentration levels in pregnant women. It is important to mention that the quality of the fT4 measurement can also explain the great variability observed in the literature. There is no question for me that the BBDR model is a gold standard for supporting different agencies in their decisions, based on biological plausibility. However, it seems that here, there is the complex harmonization of parameters derived using important statistical energy and fancy approaches. I have no doubt about the mode of action, based on a competition between perchlorate and iodine on the NIS transporters, but I am not sure that we have all the accuracy requested to conduct a risk assessment based on this complex model. The team who worked on this model put in a lot of effort.

In 2005 the NAS developed an approach which was good enough for that time. Now we have more recent studies describing the interaction or production of T3, T4, NIS, TSH and the influence of perchlorate on this regulation and the consequence of these human exposure in the newborn. We understand these interactions and can quantify those using human data. Our understanding of biology provides the opportunity to reasonably develop a mathematical description of BBDR model based on our best understanding of the biology. From my point of view, it would be a mistake not to consider it. It is not a perfect model but was built also using not perfect human data. However, from my point of view it is an innovative approach and the confidence of the model will come with time. There is no perfect model, but some are useful.

Dale Hattis, Ph.D.

Overall EPA has done a creditable job in this analysis. I do have some suggestions for improvement, as outlined in my responses to the charge questions below.

Angela M. Leung, M.D., M.Sc.

The current report provides a complex analysis of the potential effects of low-level environmental perchlorate exposure in women during early pregnancy and their offspring during childhood, and represents an immense amount of work. Compared to the model reviewed in Jan 2017, the incorporation of early pregnancy and the hypothalamic-pituitary-thyroid axis feedback loop into this model is a much more physiologic and relevant assessment of exposure effects in a particularly vulnerable population subgroup and takes into account known compensatory mechanisms resulting from low iodine and/or thyroid hormone levels. In addition, the current model utilizes an exhaustive review of recently published literature (2000-2017) regarding the relationships between maternal hypothyroxinemia during early pregnancy and neurodevelopmental outcomes among their offspring, although only five studies resulting from this search were used for the model.

The current report summarizes an approach based on two stages:

- The first stage summarizes a revised BBDR model, regarding the relationships between iodine status and thyroid hormone production in women of childbearing age, in order to predict the potential effects of maternal perchlorate exposure on maternal thyroid hormone production during early pregnancy.
- In the second stage, the extensive presentation of summaries and key findings of the 15 studies meeting criteria for Group 1 (i.e. studies that evaluated maternal serum FT4 concentrations as a continuous variable during early pregnancy and any variety of offspring neurodevelopment outcomes) offers a detailed look at the most rigorous available studies on this topic at present. These studies were further restricted into the five which had reported a significant adverse effect of neurodevelopmental outcomes in offspring born to hypothyroxinemic pregnant women (thus not studies evaluating perchlorate exposure) to inform the derivation of a perchlorate maximum contaminant level goal (MCLG). The numerous other studies in the literature on this topic were not included as they either reported non-significant findings, did not assess maternal serum

FT4 concentrations as a continuous variable, or were not intended to examine offspring neurodevelopmental outcomes.

As none of the five studies in the first approach were based in the U.S. but more importantly, does not provide extensive information regarding maternal iodine status, the report also presents an alternative population-based approach to determine the proportion of pregnant women in a perchlorate-exposed population who would be at risk for having offspring with an adverse neurodevelopment outcome, based on a given steady state of low iodine status.

Overall, the current report is extensively detailed and generally improved from that discussed in Jan 2017, although the clarity of the writing could still be improved to be relevant for a broader readership, and there remain certain circular redundancies of language that could be addressed to make the report much more concise and overall readable. The charge questions as below were also at times overlapping in nature and leaned more toward model concepts; they may have been better phrased upon consultation with perhaps a more multidisciplinary group of experts.

Although the concepts of the overall model are biologically plausible, I have noted several areas, as below, to potentially strengthen key clinical concepts used to inform the model. My comments are based on my background and perspective as a clinical endocrinologist/thyroidologist with clinical research interests in iodine nutrition, thyroid dysfunction, and thyroid disruptor exposures during pregnancy, post-partum, and early childhood.

Stephen M. Roberts, Ph.D.

There are several important improvements in the BBDR modeling and the accompanying report from the version reviewed in January 2017. Addressing the first trimester fetus as a sensitive life stage, incorporation of a TSH – thyroid hormone feedback loop, extension of the modeling to include quantitative relationships between thyroid hormone effects and neurodevelopmental outcomes, much improved presentation of results and discussion of uncertainties, and overall clarity of presentation are among the most significant changes. The rationale for key decisions is clearly explained and supporting information/data are, in general, accurately presented. Overall, the conclusions are sound and the report provides a useful means to evaluate the scientific strengths and limitations in two proposed approaches to developing a MCLG for perchlorate in drinking water.

Joanne F. Rovet, Ph.D.

Having reviewed the previous draft of BBDR Model Report for Perchlorate in Drinking Water (2016/2017), I find the current version far improved and much clearer in its presentation. In fact, it was a pleasure to read. Furthermore, the current extended version takes into account many of my earlier concerns, particularly: not modelling the HPT axis, not considering the early-in-pregnancy stage, poorly articulated downstream endpoints, use of old references, quality of presentation of results, and poor organization of report itself. Most of these issues have been satisfactorily addressed in what now appears to be a completely overhauled set of processes. The current model is bifold using both former BBDR modeling procedures to extrapolate maternal

early gestational free T4 levels from varying perchlorate exposures in a low-iodine environment and using the current epidemiologic literature on offspring outcome following maternal hypothyroxinemia exposure to extract losses in child IQ or alternative endpoints. In the ultimate analysis, potential losses from varying perchlorate levels are individually tabulated according to findings from the five best papers. The writer(s) show an excellent understanding of how to manipulate a massive amount of empirical evidence in order to present cohesive and convincing arguments. This is very impressive.

However, I still have a number of concerns, particularly the loss of any evidence and specifications for the other critical life stages, namely the later-stage fetus and the breast-versus bottle-fed baby. Granted, large-scale cohort studies of the necessary scenarios for these life stages are not as readily available as they are for those earlier in pregnancy to allow the modelers to derive the necessary numerical information for conducting the second phase of modelling, at least some attempt should have been made to estimate what is happening at these times during development. This is relevant because the brain continues to undergo thyroid hormone-dependent development past the second trimester and for some aspects of cognition and behavior, this latter development has a greater impact on overall life functioning. Note, I don't believe it was ever the intention of the former group of reviewers to remove these life stages.

Despite the excellent quality of presentation of Volume I, I was disappointed in its ending with a lack of summary and take-home message. I thought that some attempt might have been made to better combine the findings of the 5 studies into one set of data (e.g., using standard scores) and to better catalogue in a summary table the findings from remaining Group 1 studies as well as those from the other groups. I did think the author(s) at times got bogged down in the details of the paper. Furthermore, I would have liked the author(s) to discuss the clinical significance of the findings (and maybe even monetary costs); even though the effects were significant, their size was not large.

Notably, too, some critical papers were not discussed, particularly the Controlled Antenatal Thyroid Screening (CATS) study (Lazarus et al. 2012 and Hales et al. 2018) findings and the paper by Taylor (2014) from this group on perchlorate and the new paper by Dr. V.J.M Pop (not published yet) that examines trajectories of maternal hypothyroxinemia throughout pregnancy as a critical factor. Along these lines, I wonder too why the studies measuring maternal TSH primarily were disregarded as this would be at least a marker of maternal thyroid hormone insufficiency to which the fetal brain is exposed. Finally, I found the discussion of thyroid and the brain to be very cursory and based on old literature and I think the author(s) understanding of pregnancy and the fetal compartments is a bit weak.

As for the CATS study (Lazarus et al. 2012 and Hales et al. 2018), I had thought there was a paper that directly correlated the mothers' levels in the untreated group with child outcome. If this is not contained in the two papers, then it may have been from an unpublished paper I had read. But do check for correlations in the untreated group. As for the Pop paper, I don't think it's been published yet, just Endendijk (2017) which categorizes children from the same study into ADHD. As for Taylor, I at the time of my writing remember his 2014 JCEM study but it seems that this is just categorical so wouldn't make it to your Group 3. That said, it should have been included in the overall search and made it to your Group 2.

Endendijk, J., Wijnen, H., Pop, V., and van Baar, A. (2017). Maternal thyroid hormone trajectories during pregnancy and child behavioral problems. *Hormones and Behavior*, *94*, 84-92.

Hales, C., Taylor, P., Channon, S., Paradice, R., McEwan, K., Zhang, L., Gyedu, M., Bakhsh, O., Muller, I., Draman, M., Gregory, J., Dayan, J., Rees, D, and Ludgate, M. (2018) Controlled Antenatal Thyroid Screening II: effect of treating maternal sub-optimal thyroid function on childhood cognition. *The Journal of Clinical Endocrinology & Metabolism*

Lazarus, J., Bestwick, J., Channon, S., Paradice, R., Maina, A., Rees, R., Chiusano, E., John, R., Guaraldo, V., George, L., Perona, M., Dall'Amico, D., Parkes, A., Joomun, M., and Wald, N. et al.. (2012). Antenatal Thyroid Screening and Childhood Cognitive Function. *The New England Journal of Medicine*, 366, 493-501.

Taylor, P., Okosieme, O., Murphy, R., Hales, C., Chiusano, E., Maina, A., Joomun, Mohamed, Bestwick, J., Smyth, P., Pardice, R., Channon, S., Braverman, L., Dayan, C., Lazarus, J., and Pearce, E., (2014). Maternal Perchlorate Levels in Women With Borderline Thyroid Function During Pregnancy and the Cognitive Development of Their Offspring: Data From the Controlled Antenatal Thyroid Study. *The Journal of Clinical Endocrinology & Metabolism*, 99(11), 4291-4298.

4. RESPONSE TO CHARGE QUESTIONS

Question 1. General Questions: Please comment on the appropriateness of focusing the current evaluation on perchlorate's potential impact on the fetuses of hypothyroxinemic pregnant women during early gestation for the purposes of informing a perchlorate MCLG.

Hugh A. Barton, Ph.D.

The focus on the fetuses of hypothyroxinemic pregnant women during early gestation is completely appropriate and consistent with the recommendations in the US EPA SAB report from 2012-2013. The January 2017 peer review of the PBPK/PD model for end of third trimester and post-natal lactational periods also identified that the literature linking altered thyroid hormone levels with neurodevelopmental impacts was largely limited to consideration of first trimester. Thus, this model addresses the recommendations of that peer review.

Nancy Carrasco, M.D., M.S.

Yes, I agree that it is appropriate to focus on perchlorate's potential impact on the fetuses of hypothyroxinemic pregnant women during early gestation for the purposes of deriving a perchlorate MCLG, because these fetuses are the most vulnerable subjects and the most likely to suffer serious and irreversible intellectual damage if exposed to perchlorate. Therefore, a perchlorate MCLG that protects these fetuses will ensure that other vulnerable populations are also protected.

Jonathan Chevrier, Ph.D.

Fetuses of hypothyroxinemic pregnant women are likely to be particularly vulnerable to the effect of chemicals on thyroid function. Early gestation, when fetuses cannot produce thyroid hormone and thus depend on thyroid hormone of maternal origin for normal development is also likely to be a sensitive developmental period. Focus on this population and developmental stage is thus highly relevant.

Claude Emond, Ph.D.

The description of the hypothyroxinemic pregnant women is the major issue, as well as the major window of sensitivity. This recommendation was also formulated by the SAB in 2017. I believe it was justified that the EPA requested to do the analysis for the first and second stages of pregnancy as well.

Dale Hattis, Ph.D.

This seems reasonable; however, the effects of choosing various different degrees of iodide deficiency should be evaluated and reported. I would say that in general that a range for relatively conservative choices of thyroid deficiency should be made, including the 5th, 2nd, 1st, and possibly 0.1 percentiles of the US population, as projected from reasonably representative data for chronic exposures (acute effective one day exposure and/or blood level information from NHANES may need modification to achieve this goal). To do this, studies should be sought of the day to day within-individual variability of blood iodide levels.

Angela M. Leung, M.D., M.Sc.

The current report's focus remains on hypothyroxinemia, similar to the previous report discussed at the Jan 2017 meeting. However, the current report has now shifted to the offspring of women who were hypothyroxinemic during pregnancy, particularly during the first trimester, thus marking a change to an earlier insult, compared from the previous report that was primarily based on hypothyroxinemia during the post-partum period (among lactating women, breastfed infants, and formula-fed infants).

The focus on low maternal serum FT4 concentrations in early pregnancy, rather than another measure such as elevated maternal TSH concentrations, was recommended by the EPA's Science Advisory Board (2013) as the preferred marker of maternal thyroid hormone status in pregnancy. The pros and cons of utilizing hypothyroxinemia as the preferred marker of exposure were summarized at the previous meeting, and these remain the same now. These primarily included the inability to regard hypothyroxinemia in pregnancy as an independent clinical entity, but which has been demonstrated in recent literature to be associated with adverse offspring neurological outcomes.

The shift in the current report to focus on offspring neurodevelopmental measures is appropriate and marks an improvement from the previous report that assessed only serum FT4 concentrations in lactating women and infants. The current understanding of available literature suggests that these outcomes, which may be long-lasting and extend well into adulthood, are the results of low iodine status and/or thyroid hormone levels during mostly early pregnancy.

However, perchlorate exposure is of course not limited to women during early pregnancy. Notably, the lactation sub-model in the previous (Jan 2017) report has been eliminated in the current report. Although the primary focus should be early pregnancy, the early postpartum period represents a still important period of continued neurodevelopment and can be considered a secondary focus of exposure important for lifelong adverse outcomes, including neurocognitive measures. As noted in the Jan 2017 report, there are available data regarding perchlorate content in breastmilk and infant formula, albeit those should also be interpreted with their own limitations as per my previous comments.

Stephen M. Roberts, Ph.D.

In their 2013 report, the SAB recommended using a PB/PK-PD (BBDR) approach in developing a MCLG for perchlorate in drinking water, and that the EPA include thyroid hormone changes during sensitive life stages for neurodevelopment, specifically mentioning fetuses of hypothyroxinemic pregnant women and infants and neonates exposed to perchlorate through breast milk or water-based formula. The initial BBDR modeling conducted by the EPA, peerreviewed in January 2017, included these sensitive life stages, although modeling during pregnancy was limited to near term. Comments from the January 2017 peer review meeting strongly recommended that the first trimester of pregnancy be included as a sensitive life stage. The modeling effort currently reviewed is responsive to this recommendation, and in fact focuses on this life stage exclusively. The report explains that the epidemiology supporting a relationship between maternal thyroid hormone levels and neurodevelopmental outcomes is stronger for fT4 in the first trimester than later stages of pregnancy (see page 3-3). In fact, the report states, "This was confirmed by the results of EPA's literature search (summarized in Section 5) which found limited to no data regarding altered thyroid hormone levels and subsequent neurodevelopment effects on life stages other than early pregnancy." (page 1-5). The absence of data to credibly extend the BBDR modeling to neurodevelopmental outcomes for other life stages makes the decision to focus on early pregnancy appropriate in my opinion. However, it leaves unresolved the status of the other sensitive life stages — specifically, infants and neonates exposed through breast milk or water-based formula. Are they assumed to be less sensitive, and thus protected by a MCLG developed based on the first trimester fetus? If so, what information is available to support that assumption? Or is there simply not enough data to indicate the comparative sensitivity of the other life stages? If that is the case, it creates an uncertainty in MCLG development that merits additional discussion.

Joanne F. Rovet, Ph.D.

It is important that this period of development is examined, but not to the exclusion of the other sensitive periods. It is really a matter of convenience as the bulk of the cohort studies obtained maternal data at these times. I would have liked a better justification of why this period (and this period alone) is so critical. Bernal has recently shown that cerebral cortex neurogenesis takes place during this window. Perhaps some emphasis on this would rationalize this focus. However, the author(s) must be clear that further critical aspects of brain development are occurring in later windows and they are thyroid-hormone dependent. Perhaps incorporate some of the congenital hypothyroidism findings and some of the newborn screening (normal) results, especially if these were used as controls in neurodevelopmental studies. Perhaps too, include summarized findings of the studies on transient hypothyroxinemia of prematurity including those by this reviewer. This work covers the late-in-pregnancy sensitive period.

Question 2. General Questions. Please identify any additional peer-reviewed studies that could inform the BBDR modeling or the quantitative relationship of thyroid hormone levels to neurodevelopmental outcomes. If an alternative study data set would be more appropriate, please outline how such data might be used.

Hugh A. Barton, Ph.D.

Not aware of any additional studies.

Nancy Carrasco, M.D., M.S.

No comment.

Jonathan Chevrier, Ph.D.

I am not aware of studies other than those used or otherwise mentioned in this report.

Claude Emond, Ph.D.

I did not find any additional peer-reviewed studies that would add significant information to challenge this work.

Dale Hattis, Ph.D.

I didn't come across any.

Angela M. Leung, M.D., M.Sc.

For the current report, a comprehensive search was performed of published studies regarding the relationships of serum thyroid hormone concentrations and neurodevelopmental outcomes. However, the search was restricted to studies published in 2000 and later. This approach omits the important study by Haddow et al. (NEJM, 1999; PMID: 10451459), which in fact did measure maternal serum TSH, TT4, and FT4 concentrations (erroneously stated in the current report that serum TT4 and FT4 were not measured) and correlated to their offsprings' neuropsychological test scores at ages 7-9. This was one of the first reports to demonstrate an adverse effect of maternal hypothyroidism during pregnancy on childhood neurocognitive outcomes, is considered a seminal article regarding this topic, and should be included.

Stephen M. Roberts, Ph.D.

I am not aware of any additional peer-reviewed studies that would be useful for the BBDR modeling or in establishing a quantitative relationship between thyroid hormone levels and neurodevelopmental outcomes.

Joanne F. Rovet, Ph.D.

Bárez-López, S., Jesus-Obregon, M., Bernal, J., and Guadaño-Ferraz, A. (2017). Thyroid Hormone Economy in the Perinatal Mouse Brain: Implications for Cerebral Cortex Development. *Cerebral Cortex*, 1-11.

Bath, S., Steer, C., Golding, J., Emmett, P., and Raymen, M. (2013). Effect of inadequate iodine status in UK pregnant women on cognitive outcomes in their children: results from the Avon Longitudinal Study of Parents and Children (ALSPAC). *The Lancet*, 382(9889), 331-337.

Bernal, J. (2017). Thyroid hormone regulated genes in cerebral cortex development. *Journal of Endocrinology*, 232(2): R83-R97.

Casey, B. & Thom, E. (2017). Subclinical Hypothyroidism or Hypothyroxinemia in Pregnancy. *The New England Journal of Medicine*, *377*(7), 701.

Casey, B., Thom, E., Peacemann, A., Varner, M., Sorokin, Y., Hirtz, D., Reddy, U., Wapner, R., Thorp, J., Saade, G., Tita, A., Rouse, D., Sibai, B., Iams, J., Mercer, B., Tolosa, J., Caritis, S., and VanDorsten, J. Peter et al. (2017). Treatment of Subclinical Hypothyroidism or Hypothyroxinemia in Pregnancy. *The New England Journal of Medicine*, *376*, 815-825.

Lazarus, J., Bestwick, J., Channon, S., Paradice, R., Maina, A., Rees, R., Chiusano, E., John, R., Guaraldo, V., George, L., Perona, M., Dall'Amico, D., Parkes, A., Joomun, M., and Wald, N. et al.. (2012). Antenatal Thyroid Screening and Childhood Cognitive Function. *The New England Journal of Medicine*, 366, 493-501. (and later studies now in publication)

Pop et al 2017 Longitudinal trajectories ... in thyroid function -? This study may not be published yet. I suggest you write to him perhaps about the status of the paper.

Taylor, P., Okosieme, O. E., Murphy, R., Hales, C., Chiusano, E., Maina, A., Joomun, M., Bestwick, J. P., Smyth, P., & Paradice, R. (2014). Maternal perchlorate levels in women with borderline thyroid function during pregnancy and the cognitive development of their offspring: data from the controlled antenatal thyroid study. *The Journal of Clinical Endocrinology & Metabolism*, 99(11), 4291-4298. (cited but not properly discussed)

Question 3. <u>BBDR Modeling to Predict Changes in Thyroid Hormone Levels in Early Pregnancy.</u> Please comment on the assumptions, strengths and limitations of methods and parameters by trimester for:

Question 3A. Determining the quantitative relationships between oral intake and serum levels of perchlorate during pregnancy under continuous exposure assumptions.

Hugh A. Barton, Ph.D.

Model simulations compare well with data for non-pregnant women (Section 2.1 in Appendix A) and males. Adjustments of physiological parameters are made for pregnancy, so in the absence of other data, it is appropriate to assume that the model reasonably predicts perchlorate pharmacokinetics during pregnancy.

Nancy Carrasco, M.D., M.S.

The topic of BBDR modeling and the fields of pharmacokinetics and pharmacodynamics are outside my area of expertise; I am therefore unable to comment on this topic.

Jonathan Chevrier, Ph.D.

BBDR modeling being outside of my area of expertise, I do not feel that I can comment on the assumptions, strengths, and limitations of the method and parameters.

Claude Emond, Ph.D.

It is reported in the document that "Several short-term (two-week exposure duration) studies have reported that exposures decreases in iodide uptake, <u>but not with changes in levels of thyroid hormones in the blood"</u> (V1, page 1-2, p15) This is because the reserve of T4 is relatively high. What would the dose that will really impact the homeostasis and spent the dose causing a hypothyroxinemia?

Dale Hattis, Ph.D.

The relationship between external exposures to perchlorate and serum levels of thyroid hormones in the current EPA analysis appears to be primarily inferred from a recent paper of Steinmaus et al. (2016). This is a good paper based on extensive relevant observations of the association between serum thyroid hormone levels and urinary perchlorate observations (the latter, a good indicator of recent exposure to perchlorate).

Unfortunately, the Steinmaus analysis choses to use a log-transform of the urinary perchlorate in its regressions, e.g., serum thyroid hormone concentration in the blood (that is, total T4, fT4, and the related variable TSH) = Log10(urine perchlorate) + other regression variables.

My past experience is that there are few, if any, biological mechanisms that lead naturally to an expectation of a log-linear dose response relationship. Instead, mechanistically based Michaelis-Menten enzyme kinetics leads more naturally to another mathematical form:

$$Effect = Emax*[C]/(Km + [C])$$

Where [C] is the substrate concentration (i.e., perchlorate in this case), Emax (change in thyroid hormone concentrations) is the maximum effect that can be produced at the the limit of high [C], and Km is a constant

For convenience in regression analysis, the Log(10)[C] in the Steinmaus et al. (2016) regression analyses could be replaced by:

$$[C]/(Km + [C]),$$

where an optimal value of Km for the regression can be found, by trial and error, using multiple runs of the regression with different candidate values of Km. This optimality can be judged by maximizing the R squared statistic.

Log transformations of both dependent and independent variables have a long and hallowed tradition in analysis of epidemiological data. However, while there can be some statistical benefit in normalizing a dependent variable by log transformation, this does not carry forward to the domain of independent variables. There can be no general expectation for no improvement in the properties or accuracy of regression analysis from making the distribution of an independent variable closer to normal. Instead, the analyst will improve the description of the real causal relationship most by having the fitted equation resemble as closely as possible the real causal relationship that gave rise to the observations.

Angela M. Leung, M.D., M.Sc.

The perchlorate sub-model in Figure 4 of the main report, as well as Section 1.2 of Appendix A, were reviewed. Appendix A states that perchlorate ingestion is not metabolized, thus is assumed to be 100% absorbed and equal to the steady state delivery to plasma. Available literature appears to support this and demonstrates that perchlorate is excreted intact in the urine with 95% recovery within 72 hours (Soldin et al, PMID 11477312). Given this, the assumption that nearly 100% of ingested perchlorate will circulate in plasma unchanged appears to be appropriate.

Stephen M. Roberts, Ph.D.

The perchlorate sub-model treats perchlorate as being delivered directly to the central compartment (no transformation in the GI tract and 100% absorption). This simplification could affect simulation of short-term perchlorate kinetics, but is less of an issue for longer-term model predictions most relevant to the BBDR modeling. Modeling has been strengthened by the addition of a number of refinements, including protein binding of perchlorate in blood and distribution into red blood cells. One limitation in modeling perchlorate kinetics in pregnancy is the absence of suitable kinetic data from pregnant women. As a result, data from non-pregnant women and men had to be used for comparison with model predictions. Changes in the clearance rate of perchlorate during pregnancy were estimated from an empirical relationship between gestational age and glomerular filtration, and the relationship between glomerular filtration rate and iodine clearance. These approaches to the absence of PK data from pregnant women are reasonable but contribute to uncertainty in perchlorate blood concentration predictions.

Joanne F. Rovet, Ph.D.

While Figure 4 seems reasonable to me from the point of view of the mother, it does not account for the fetus and for the fetal brain, which ultimately need their thyroid hormone. There is no accounting for the different sacs and how perchlorate may interfere with thyroid iodide to the fetus via the coelomic sac (earliest pregnancy) and amniotic sac (later). Similarly, there is no system that models thyroid hormone from the mother to the fetal brain and into the brain via the blood-brain barrier (to cortex) and choroid plexus (to subcortical regions and posterior cortex). It is said that NIS receptors are found in the choroid plexus, so what happens if these are blocked?

Question 3. <u>BBDR Modeling to Predict Changes in Thyroid Hormone Levels in Early Pregnancy.</u> Please comment on the assumptions, strengths and limitations of methods and parameters by trimester for:

Question 3B. Estimating statistical distributions of specific biochemical parameters that determine serum perchlorate concentrations, urine clearance of iodide and perchlorate, and thyroid iodide uptake for purposes of estimating the effect of environmental levels of perchlorate on maternal fT4 concentrations.

Hugh A. Barton, Ph.D.

Estimation of statistical distribution is not this reviewer's area of expertise. It was not entirely clear how the use of some parameters as a specified lower percentile, e.g., CLFUP as 2.5th percentile value, fit together with the distributional aspects.

Nancy Carrasco, M.D., M.S.

The topic of BBDR modeling and the fields of pharmacokinetics and pharmacodynamics are outside my area of expertise; I am therefore unable to comment on this topic.

Jonathan Chevrier, Ph.D.

Again, BBDR modeling being outside of my area of expertise, I do not feel that I can comment on the assumptions, strengths, and limitations of the method and parameters.

Claude Emond, Ph.D.

This is a very sophisticated approach, using all those statistics, but in the end, I am not sure about the improvement (advancement) of these sophisticated approaches. The explanation during the public comment brought some important response about what they do and increase the confidence but also limitation of database available.

Dale Hattis, Ph.D.

See comment to Question 3A.

Angela M. Leung, M.D., M.Sc.

I reviewed the values summarized in Table 1, but this is not my area of expertise and cannot comment further.

Stephen M. Roberts, Ph.D.

Variability in maternal fT4 concentrations was estimated based upon studies with fT4 data from 12, 13, and 16 weeks of gestation. Although the number of available studies was small (3), the use of variability data from human subjects is an important strength. Data were assumed to be lognormally distributed, and a geometric standard deviation (GSD) was used to quantify variability. As the report points out (page 4-6), although the data were right-skewed, a distribution other than lognormal may better describe the variation in fT4. Time and resources permitting, it would be useful to explore other distributions, as the population variability in fT4 is important in predicting perchlorate effects at various percentiles.

Joanne F. Rovet, Ph.D.

This is beyond my competence.

Question 4. <u>BBDR Modeling to Predict Changes in Thyroid Hormone Levels in Early Pregnancy.</u> Please comment on the assumptions, strengths and limitations of the uncertainty analyses of the parameters, particularly with regard to availability of data supporting parameter assumptions.

Hugh A. Barton, Ph.D.

In general, the modelers provided descriptions of the data sources they relied upon to establish the many different aspects of the model. They did classic sensitivity analyses as well as trying to assess uncertainties or simply predictive differences with different assumptions, particularly iodide intake levels. Data to estimate different parameters and test of the model are generally limited, so the model can only be as strong as the data. The complexity of the model including biological feedback processes for thyroid hormones and pregnancy related changes as well as linking the model predicting to neurodevelopmental hormone-response relationships means it is challenging to communicate and evaluate the uncertainties. However, this biological modeling approach allows one to begin to describe where the uncertainties lie in contrast to the simpler approaches based upon a selected LOAEL or NOAEL that simply apply default uncertainty factors for various things.

Nancy Carrasco, M.D., M.S.

The topic of BBDR modeling and the fields of pharmacokinetics and pharmacodynamics are outside my area of expertise; I am therefore unable to comment on this topic.

Jonathan Chevrier, Ph.D.

I do not feel qualified to answer questions 4-7 and prefer not to comment.

Claude Emond, Ph.D.

The strategy used to consider the uncertainty and the variability was correctly applied. They analyzed all the parameters as mentioned on page A-97. The outcome was the variation of the fT4. Here they reported only parameters with relative change higher than 0.1. Which was the strategy to adopt.

Dale Hattis, Ph.D.

The document has a quite extensive qualitative discussion of the uncertainties of the analysis. It could be improved by drawing some quantitative inferences about how large the uncertainties from different sources are likely to be.

Angela M. Leung, M.D., M.Sc.

The report described several uncertainties in Section 3.5:

- Placental and fetal iodine and thyroid hormone content: Page 43 of the report states that the absolute contribution of iodine and thyroid hormone stores in the placenta and fetus toward those in the mother are likely insignificant, thus there are not separate placental and fetal sub-models. I agree that this is likely appropriate, since the fetal thyroid does not begin to develop structurally until approximately 10-12 weeks of gestation, and remains very small in size (relative to the maternal thyroid) with likely very little iodine and thyroid hormone content throughout gestation.
- Iron deficiency: Page 43 describes the potential impact of iron deficiency on hypothyroxinemia as an uncertainty. Although iron deficiency anemia is the most common cause of anemia during pregnancy, we do not seem to observe hypothyroxinemia commonly in the clinical setting among women with iron deficiency. I would agree that maternal iron deficiency is unlikely to be a significant contributor for the purposes of the model and does not have to be accounted for. Of note, the 2016 ATA pregnancy guidelines also do not mention iron deficiency.
- Coexposures: Page 45 states the potential uncertainties of the model resulting from coexposures to other environmental and dietary thyroid disruptors. Accounting for wide number of these unmeasured substances is impossible, and thus it is appropriate to leave this issue as a limitation of any exposure model, as was stated in the report to be present also in the NHANES datasets. One consideration, however, is thiocyanate as the one exposure with sufficient available data to likely further improve the perchlorate model (see my comments to Question #8).
- Competitive effect at low perchlorate concentrations: Page 45 describes the
 uncertainty of the model based on the effect perchlorate on iodine uptake as mediated by
 NIS at low perchlorate levels. It is appropriately stated that current understanding
 demonstrates no additional magnification of this effect even at lower perchlorate
 concentrations.
- **Potentiation of other thyroid disease**: Page 46 lastly describes the potential uncertainty of environmental perchlorate exposure on potentiating the development of other thyroid diseases, such as Hashimoto's thyroiditis. Although this is certainly possible, current understanding is limited to lacking on this topic, thus it is appropriate to leave this as an uncertainty of the model.

Stephen M. Roberts, Ph.D.

A semi-quantitative analysis of uncertainty and variability of the parameters was conducted through a Local Sensitivity Analysis presented in Appendix A. Although ranges of values were not determined in a statistically rigorous way, the analysis nevertheless provides a rough estimate of the range of potential values compared with the central estimate. This analysis is adequate for the purposes of the report.

Joanne F. Rovet, Ph.D.

I am not too sure what is meant by the statement "Increased urinary clearance of both iodide and perchlorate during pregnancy (why?), described by the model, have the conflicting effect of both reducing ... so these two components of pregnancy-related changes will cancel each other out to some extent".

Question 5. BBDR Modeling to Predict Changes in Thyroid Hormone Levels in Early Pregnancy. Please comment on the utility of the BBDR model for predicting variability in fT4 levels in the population (e.g., percentiles for different thyroid hormone levels) at varying levels of iodide intake.

Hugh A. Barton, Ph.D.

Since changes in fT4 levels are a key output of the model, its ability to predict them for varying levels of iodide intake is important.

The comments submitted by American Water Works Association (AWWA), based upon a review by Gentry et al., states that these levels are not adequately predicted. In response to this concern, I undertook some review of the modeled median fT4 levels during pregnancy without perchlorate exposure. It is difficult to understand what is going on with different values ranging from about 10-15 pmol/L in different figures and tables at gestation weeks 12-16 (e.g., Fig A-57 14-15 pM; Table 2 10-11 pM for 170 μ g/day iodide; Fig 5 \sim 10.5 pM). Since Fig A-57 represents data from studies and appears well simulated, it is not clear what is different in Table 2 and Fig 5.

Gentry et al. ran the model to compare results with three studies, and presumably their findings contributed to their comments that the model did not adequately predict. The problem for the Steinmaus et al. 2016 study was that the model under predicted the extent of perchlorate-mediated changes in fT4, while for Greer et al. 2002 and Tellez Tellez et al. 2005 predictions were consistent with the observed absence of change, but the model under-predicted fT4. Thus, it isn't clear that the model inadequately predicts, or if it does, it appears to be insufficiently responsive to perchlorate-mediated effects.

Nancy Carrasco, M.D., M.S.

The topic of BBDR modeling and the fields of pharmacokinetics and pharmacodynamics are outside my area of expertise; I am therefore unable to comment on this topic.

Jonathan Chevrier, Ph.D.

I do not feel qualified to answer questions 4-7 and prefer not to comment.

Claude Emond, Ph.D.

The 1T BBDR explores the influence of perchlorate to reduce the iodine to transfer inside the thyroid tissue using transporter NIS before and during the 1st trimester of pregnancy. This iodine was supposed to be transferred in the thyroid tissue for the production of T3 and T4. The model has been parametrized and assessed for the sensitivity analysis and then the sensible parameters more than 0.1 were assessed for uncertainty and variability using an approach published by

Sweeney et al. (2003).

Compare to the previous version, EPA improved clarity/transparency, model uncertainty, hCG, NIS Km, perchlorate impact on fT4 and thyroid hormones, plasma protein binding, model precision, rest of body compartment, significance of effect, TSH T4 set point, uncertainty and sensitivity analysis.

The negative point for this model is that it is limited to the first trimester. I do not know why they did not model for the whole pregnancy time.

On page A-68 it is mentioned that during the gestation "A possible mechanism for increased potency is that hCG has been shown to increase endothelial permeability (Rodewald et al., 2009), which could allow more fT4 to penetrate and act on the hypothalamus if the same mechanism occurs in that tissue. While data to specifically characterize such a mechanism are not available. That is an important limitation that needs to be explained on how confident we are regarding this mechanism of action.

Overall, <u>I am confident enough with this model</u>. For me this model can be used, but it should be challenged for more confidence. It would be a mistake not to use the model for the determination of Maximum Contaminant Level Goal (MCLG) estimation. This approach is more biological relevant than to use NOAEL, but at this point I would suggest adding an uncertainty factor until the model is challenged.

Dale Hattis, Ph.D.

See detailed comments on the variability analysis in my response to question 7 below. A priori I have no difficulty with the use of the model as now done in the document.

Angela M. Leung, M.D., M.Sc.

The model's incorporation of other factors, such as the TSH feedback loop and effect of bHCG, strengthens the ability to predict maternal serum FT4 levels, at varying levels of iodine intake. The model's estimation of dietary iodine intake is summarized in Appendix Section 2.2.1, which is based on a spot urinary iodine concentration collected from NHANES participants and adjusted for known or estimated daily urine volumes.

However, there can be substantial diurnal and day-to-day variations in urinary iodine concentrations in a given individual (Rasmussen et al, PMID 10359497). Given this, it is not surprising that the current report found no relationship between dietary iodine estimates and serum FT4 concentrations in the NHANES datasets. The accuracy of the iodine intake values is a limitation to the model predicting serum FT4 concentrations. Overall, the challenge is that individual iodine status is difficult/impossible to estimate; only population iodine status can more reliably be determined.

The present report can also consider the points made in the following article by Brucker-Davis and colleagues demonstrating no effect of iodine supplementation in later pregnancy (albeit later

pregnancy) on serum FT4 concentrations (PMID 24847452), which was reviewed briefly for *Clinical Thyroidology* and *Clinical Thyroidology for the Public* as below: https://www.thyroid.org/patient-thyroid-information/ct-for-patients/vol-6-issue-12/vol-6-issue-12-p-4-5/.

https://www.thyroid.org/wp-content/uploads/publications/clinthy/clinthy_v2510.pdf

Stephen M. Roberts, Ph.D.

As indicated in Figure A-57, the BBDR model predicts variability in fT4 levels as a function of iodide uptake reasonably well.

Joanne F. Rovet, Ph.D.

It seems reasonable, although I still had difficulty reading the simulation graphs (p3-11).

Question 6. <u>BBDR Modeling to Predict Changes in Thyroid Hormone Levels in Early Pregnancy</u>. Please comment on the robustness, precision and sensitivity of the model, and how these factors affect the model's ability to predict changes in fT4 at low perchlorate doses. Consider whether a perchlorate dose range exists for which the modeling predictions would be highly uncertain.

Hugh A. Barton, Ph.D.

EPA provides a wide range of information on fits to different data sets and sensitivity analyses. Not surprisingly, the model fits some data better than others, but it is not obvious that there is a consistent problem in a specific area of biology or dose range. Gentry et al., in their comments for AWWA, question whether the model should be relied upon for small changes in model outputs (e.g., <1%), such as fT4. Given the variability in existing data and the complexity of the decisions involved in putting together this model, it does seem reasonable to be concerned that very small predicted changes in model outputs might be more difficult to characterize for how well supported they are compared to somewhat larger change. None-the-less, the model represents the most complete analysis of the available data, so provides a valuable tool for considering development of an MCLG.

Nancy Carrasco, M.D., M.S.

The topic of BBDR modeling and the fields of pharmacokinetics and pharmacodynamics are outside my area of expertise; I am therefore unable to comment on this topic.

Jonathan Chevrier, Ph.D.

I do not feel qualified to answer questions 4-7 and prefer not to comment.

Claude Emond, Ph.D.

Several parameters have been adjusted and statistically optimized because of missing measured parameters. However, even though we performed this optimization, we can see that the relation between TSH and fT4 are still compared to a cloud of data points from biomonitoring. The figures (Fig 5 Vol 1, page 3-11; figure A-44 A-46 Vol 2 page A-70), precise that the simulation of TSH showed that an increase of perchlorate exposure result in a decrease of fT4 resulting in an increase of TSH. Nevertheless, we can see that the model simulation curve is in the middle of a cloud of data point obtained by biomonitoring of a dataset. Meanwhile, what we observe is it the best curve corresponding to the biological relevant to the reality and how confident I am with this prediction. At the end, maybe an uncertainty factors is required.

A sensibility analysis has done for the parameters of the model and then from the parameters identify more sensitive, a second analysis in regard of the uncertainty and variability has been performed. The model is usable to determine the Maximum Contaminant Level Goal (MCLG). However, more data need to be generated to improve the confidence of the predictability for this

model. In addition, the mass balance of the 1T BBDR model works which was not the case last year with the 3T BBDR model.

Dale Hattis, Ph.D.

I have no problem with the current treatment of this issue in the document. There is some reason for concern however about the accuracy of the current model at very low levels of iodide intake where the induction of TSH may or may not be accurately represented by the current model. There will clearly be some chronic reduction in internal stores of iodide and the response of the system under those conditions has not been clearly tested. However, low perchlorate dose levels do not, in my opinion, give rise to similar concerns.

Angela M. Leung, M.D., M.Sc.

- **Dietary iodine**: Comments as above in question #5.
- **Iodine intake in non-pregnant vs. pregnant women**: The results shown in Section 3.4 and Figure 5 show example outputs from the BBDR model of non-pregnant individuals and pregnant women. It is unclear to me whether the model takes into account the increased iodine need in pregnancy (extra 70 mcg/day), compared to non-pregnant adults (see Table 1 in Leung et al, PMID 22108279), that U.S. pregnant women are advised to be (albeit not uniformly) receiving (Alexander et al, PMID 28056690). Section 3.3 does state that the model adjusts for the increased serum T4 concentrations in pregnancy, for which the increased iodine need is one reason underlying this.
- I defer to the other reviewers regarding the remainder of the model.

Stephen M. Roberts, Ph.D.

As the report points out, data in humans with which to compare BBDR model predictions for perchlorate effects on fT4 are very limited. Appendix B shows a comparison of BBDR model predictions with fT4 data and perchlorate exposure from Steinmaus et al. Those comparisons show some difference in the closeness of the model prediction with Steinmaus et al. data with perchlorate dose, and overall the model appears to under-predict changes in fT4 with perchlorate dose. However, there are some important drawbacks to this comparison due to limitations in the Steinmaus et al. study, including lack of concurrency in perchlorate exposure estimation and fT4 measurements.

Joanne F. Rovet, Ph.D.

One concern I had throughout the report is why perchlorate dose increases by 1 unit until 5 micrograms/kilo/day and then jumps to 10. Why?

Question 7. BBDR Modeling to Predict Changes in Thyroid Hormone Levels in Early Pregnancy. The revised BBDR model incorporates a TSH feedback loop defined by an equation from Hadlow et al. (2013) (J Clin Endocrinol Metab, 98(7): 2936-2943), with an adjustment factor to match specific data sets or population percentiles, to describe the relationship between fT4 and TSH.

Question 7A. Please comment on the assumptions, strengths and limitations of this approach to incorporate a TSH feedback loop into the BBDR model.

Hugh A. Barton, Ph.D.

Appeared reasonable.

Nancy Carrasco, M.D., M.S.

The topic of BBDR modeling and the fields of pharmacokinetics and pharmacodynamics are outside my area of expertise; I am therefore unable to comment on this topic.

Jonathan Chevrier, Ph.D.

I do not feel qualified to answer questions 4-7 and prefer not to comment.

Claude Emond, Ph.D.

Because the TSH is a hormone, responsible for the retro feedback the production of T4 is essential in the BBDR model.

Page A-95: (improvement of the 3T model) EPA was able to describe this feedback control of TSH which is great. This new version of 1T model provided the opportunity for the EPA to increase the accuracy of 3T model reducing from 100 to 50 μ g/d iodine intake using the 1T model.

The problem seems more the quality of the data showing important variability, which makes it difficult to get the better accuracy of the model. The TSH feedback is important and has been demonstrated when the level of iodine decrease below a critical point.

Dale Hattis, Ph.D.

I agree that the interindividual variability distribution for fT4 should be presumed to be lognormal. However, the approach for combining estimates of variability from different datasets shown in Table 5 (p. 49) is not correct. Geometric standard deviations should never be simply averaged. Variances (the squares of the standard deviations) should be used as the basis for

calculating weighted averages. In this case, because the GSD estimates from different data sets refer to lognormal distributions, the variances represent the variances of the distributions of the logarithms of the fT4 levels.

Delving into the detailed numbers provided in Table 5 requires some interpretation. Because the numbers in the second and third columns of the table are all less than 1, they cannot represent GSDs. My best guess is that they represent standard deviations of the logarithms of the underlying distributions of fT4 levels. Corresponding GSDs would have to be the anti-logs of these values, e.g., $10^{\text{table values in Columns 2-3}}$. Given this assumption/guess, Table A on the next page gives my inferences for combined log(GSDs) for the different cells in Table 5. (Results are expressed to many more significant figures than are warranted to allow precise replication of the calculations. The accompanying Excel spreadsheet shows the numerical derivation of these estimates.

It can be seen in the results in Table A that, as it happens, there are very small differences between these results of this corrected combination of lognormal distributions from the results provided in the initial Table 5 given in the document. Nevertheless, I believe it is important to correct the methodology and presentation of results and to revise the subsequent table based on the altered table 5 because EPA will not wish to provide a basis for later technical challenge to the policy-relevant risk estimates that will eventually be derived.

Table A						
Recalculated Values for Table 5 Based on Combining Lognormal Variances Rather than GSDs						
	Log Variance	Log Variance		<u>Calc</u> log(GSD)	<u>Calc</u> log(GSD)	
	from 2.5th percentile	from 97.5th percentile		from 2.5th percentile	from 97.5th percentile	Combined estimate of
	estimate	estimate	Combined	estimates	estimates	log(GSD)
	0.024320403	0.02286144	0.023590921			
	0.019912032	0.028224	0.024068016			
	0.015592517	0.032634423	0.02411347			
	0.013384176	0.011487552	0.012435864			
Weighted average						
variance	0.01847841	0.027524703	0.023001556	0.135935315	0.165905704	0.15166264
	0.02042041	0.02515396	0.022787185			
	0.01687401	0.008918914	0.012896462			
Weighted average						
variance	0.01888243	0.018113251	0.018497841	0.137413356	0.134585479	0.136006767

Angela M. Leung, M.D., M.Sc.

It is appropriate for the revised model to include considerations of the hypothalamic-pituitary-thyroid feedback loop, in which serum TSH concentrations will be simulated based on predicted serum FT4 concentrations, for use in the feedback loops shown in Figure 4, specifically the action of TSH on thyroidal NIS.

However, the following assumptions should be further clarified: 1) the stimulatory action of TSH on NIS should also be in the perchlorate sub-model, since it is the same NIS in both the

perchlorate and iodide sub-models; 2) the inhibition of perchlorate on NIS in the iodide sub-model should be technically from the perchlorate content in thyroid plasma, rather than NIS, in the perchlorate sub-model.

It should also be noted that there is some variation in the TSH feedback mechanism amongst individuals (i.e. there are likely not a discrete FT4 setpoint at which increased TSH is universally triggered).

Stephen M. Roberts, Ph.D.

Incorporation of a TSH feedback loop into the model is an important addition. I have no technical comments on the approach used for TSH feedback loop modeling.

Joanne F. Rovet, Ph.D.

I am not too sure if the TSH feedback loop is properly incorporated and how, but I may be wrong. Note the Hadlow paper shows sex and age differences. Were these values incorporated into the model? Are the various transporters incorporated into the model? Are individual differences in sensitivity of TSH incorporated into the model, as mentioned on page 3-9? What about the assumption (mine) that continued exposure to low iodine and perchlorate may put the hypothalamus and pituitary into overdrive and create a form of resistance, perhaps leading to later hypothyroidism, which can happen during pregnancy when the system is stressed. Is this being accounted for in the model? Interestingly, these cases were eliminated in the second part of the analysis.

Question 7. BBDR Modeling to Predict Changes in Thyroid Hormone Levels in Early Pregnancy. The revised BBDR model incorporates a TSH feedback loop defined by an equation from Hadlow et al. (2013) (J Clin Endocrinol Metab, 98(7): 2936-2943), with an adjustment factor to match specific data sets or population percentiles, to describe the relationship between fT4 and TSH.

Question 7B. Noting the reliance on the Hadlow et al. (2013) study, please comment on whether there are other studies that should be considered and describe how they would improve the analysis.

Hugh A. Barton, Ph.D.

No comment.

Nancy Carrasco, M.D., M.S.

The topic of BBDR modeling and the fields of pharmacokinetics and pharmacodynamics are outside my area of expertise; I am therefore unable to comment on this topic.

Jonathan Chevrier, Ph.D.

I do not feel qualified to answer questions 4-7 and prefer not to comment.

Claude Emond, Ph.D.

I am not aware of any other publication that might improve the analysis.

Dale Hattis, Ph.D.

See comment to Question 7A.

Angela M. Leung, M.D., M.Sc.

The classic log-linear relationship between serum TSH and FT4 concentrations has long been recognized, which the Hadlow et al. article used to define this feedback loop in the current model does not support. The report does not sufficiently describe the reasons why this equation comprised of two sigmoidal curves was chosen to model the relationship between TSH and FT4. A commentary of the Hadlow article by Dr. Elizabeth Pearce was published in *Clinical Thyroidology* (https://www.thyroid.org/professionals/ata-publications/clinical-thyroidology/july-2013-volume-25-issue-7/clin-thyroidol-201325156-157/), which summarizes the strengths and

limitations of this paper, as well as citations of three other papers (references 1-2) which can also be considered.

Stephen M. Roberts, Ph.D.

I am not aware of other studies that should be considered to improve the analysis.

Joanne F. Rovet, Ph.D.

Perhaps check out the Controlled Antenatal Thyroid Screening (CATS) data.

Question 7. BBDR Modeling to Predict Changes in Thyroid Hormone Levels in Early Pregnancy. The revised BBDR model incorporates a TSH feedback loop defined by an equation from Hadlow et al. (2013) (J Clin Endocrinol Metab, 98(7): 2936-2943), with an adjustment factor to match specific data sets or population percentiles, to describe the relationship between fT4 and TSH.

Question 7C. Please comment on the approach for characterizing inter-individual variability in relevant populations from which the epidemiological data were obtained.

Hugh A. Barton, Ph.D.

No comment.

Nancy Carrasco, M.D., M.S.

The topic of BBDR modeling and the fields of pharmacokinetics and pharmacodynamics are outside my area of expertise; I am therefore unable to comment on this topic.

Jonathan Chevrier, Ph.D.

I do not feel qualified to answer questions 4-7 and prefer not to comment.

Claude Emond, Ph.D.

The variability of the hormones is certainly the major factor affecting the level of confidence for the validation of this BBDR model. An improvement would be to use a better analytical method for measurements of TSH, fT4 and total T4.

Dale Hattis, Ph.D.

See comment to Question 7A.

Angela M. Leung, M.D., M.Sc.

The report acknowledges several areas of potential inter-individual variability:

- **NIS**: It is reasonable to state that the degree of potential variation in NIS structure and/or regulation across individuals is unknown.
- **TSH response**: It is reasonable to state that there may be inter-individual variability in the magnitude of a TSH response following perchlorate exposure, due to the stated differences in genetics, subclinical thyroid dysfunction, age, gender, cigarette smoking, coexposures, and likely other factors. The acknowledgement that these are likely

- contributors, but which remain unable to be further built into the present model, is sufficient.
- There are also nonmeasured factors such as genetics and coexposures that may be important. Any variability in the above factors and others is best minimized with large epidemiologic datasets. Unless otherwise noted, it is a reasonable assumption that the datasets used to build the current model are appropriate.

Stephen M. Roberts, Ph.D.

I have no comments on the approach used to characterize inter-individual variability in these populations.

Joanne F. Rovet, Ph.D.

This represents a definite improvement in the approach. The authors have been very thorough and systematic. Their work here represents one of the best compilations of the field.

Question 8. BBDR Modeling to Predict Changes in Thyroid Hormone Levels in Early

Pregnancy. Since the observational thyroid hormone data that are used to calibrate the model derive from populations exposed to goitrogens other than perchlorate, EPA has made an assumption that the model parameters may implicitly account for exposures to these other goitrogens. As such, the exposure to perchlorate is assumed to be effectively added to this background goitrogen exposure as discussed in Chapter 3.5 of the report.

Question 8A. Please comment on the validity of this assumption and the extent of uncertainty associated with this assumption.

Hugh A. Barton, Ph.D.

This assumption appears reasonable because the responses observed in the human population reflect the full range of causes of population variability, e.g., genetics, life stage, co-exposures to goitrogens, and variations in iodide intake. While intellectually it would be interesting to understand the interplay among all these factors, it does not appear necessary for current purposes. For the responses to perchlorate to be substantially incorrectly attributed to perchlorate, it would have to be the case that the levels of perchlorate exposure were very highly correlated with exposures to other goitrogens.

Nancy Carrasco, M.D., M.S.

The topic of BBDR modeling and the fields of pharmacokinetics and pharmacodynamics are outside my area of expertise; I am therefore unable to comment on this topic.

Jonathan Chevrier, Ph.D.

This may be the case if one assumes that samples used in studies used to generate the data were representative of the U.S. population. This means that the distribution of all factors that could modify the relations between exposure to perchlorate and fT4/neurodevelopment should be similar in study samples as it is in the general U.S. population. For example the subsample of individuals selected from the Greer et al. study that was used for the calibration. The study itself is subject to the same issues. The study included only 37 individuals and so I find it difficult to believe that the distribution of exposure to goitrogens and other factors that may modify the effect of perchlorate would be the same in these individuals as they would be in the general U.S. population. In other words, this sample is unlikely to be representative of the U.S. population. Given the subsample of the study that was used did not appear to have been selected using a probabilistic sampling design and considering the modest sample size reported the study, EPA's assumption may be over-optimistic. EPA may want to consider applying a safety factor to derive the MCLG to account for exposure to other chemicals that may modify the effect of perchlorate.

Claude Emond, Ph.D.

No comment at this time.

Dale Hattis, Ph.D.

This seems to me to be a reasonable assumption.

Angela M. Leung, M.D., M.Sc.

Please see my comments regarding exposures to other thyroid disruptors in Question #4. The assumption that the datasets used to calibrate the model also contained exposures of unaccounted substances is reasonable.

Specifically, however, thiocyanate is the one goitrogen that may deserve further consideration for incorporation into the model. Thiocyanate is a byproduct of cigarette smoke and present naturally in certain *Brassica* vegetables, thus is a potentially common and ubiquitous exposure. Like perchlorate, thiocyanate inhibits iodine uptake mediated by NIS, though with lower affinity. There are some limited but sufficient data regarding thiocyanate to potentially use in further strengthening the model's assumptions regarding coexposures. These data include measured thiocyanate exposures in various early pregnancy cohorts, including NHANES.

Stephen M. Roberts, Ph.D.

The assumption is valid — the issue is the extent to which the available data adequately reflect variability in exposure to other goitrogens. This is a source of uncertainty in the model, but not so great as to negate the utility of these data for model calibration.

Joanne F. Rovet, Ph.D.

I'm not too sure what this means.

Question 9. <u>Identification of Published Literature and Quantitative Relationship of</u>
<u>Thyroid Hormone Levels to Neurodevelopmental Outcomes</u>. EPA conducted a three-step literature review, which identified 15 studies with information that could inform the quantitative relationship between thyroid hormone levels and neurodevelopmental outcomes.

Question 9A. Please comment on whether EPA has clearly identified the criteria to identify studies through each of the three steps of the literature review, and the adequacy of the strategy for conducting the literature search. Are these criteria scientifically supportable, and did EPA apply them properly?

Hugh A. Barton, Ph.D.

The strategy for the literature search and the criteria for categorizing the studies into three groups are clear and scientifically supported.

The search strategy initially appeared too narrow in that six additional references were added from the previous SAB review to the 49 identified through searching. Of the six, four were category 3 and thus found not to provide relevant information. Two were category 1, with one published in 1999 (before the 2000 – 2017 search period) and one in 2011, during the search period. Thus, the search appears to have been somewhat stronger than it initially appeared. But, if the search is updated, it may be worth considering whether other search terms or a broadening of the search time period would be beneficial.

Some commenters suggested that the criteria were not applied correctly in the determinations of categories, so EPA should review the decisions to insure they were appropriate.

Nancy Carrasco, M.D., M.S.

Although I am no expert on issues related to the quantitative relationship between thyroid hormone levels and neurodevelopmental outcomes, it seems to me that, yes, EPA has clearly identified the criteria for identifying relevant studies through each of the three steps of the literature review. The strategy for conducting the literature search appears to be adequate, to the best of my knowledge. I think the criteria employed by EPA are scientifically supportable and that EPA used them properly.

Jonathan Chevrier, Ph.D.

The literature review strategy is well-described, but some details are lacking. For instance, there is no information about the number of individuals who were involved at each step, whether more than one person reviewed the studies identified after running the searches (ideally there would be at least two people) and how disagreements were resolved. It would be preferable to use standard methods used for systematic reviews.

The fact that some search strings were restricted to paper titles, while others were not, is somewhat puzzling and raises the possibility that some papers may have been missed. Google search can indeed generate an unreasonably large number of hits but PubMed is usually more restrictive when using boolean terms, which was confirmed to me when I used some of the search strings listed in the report. I also wonder why "thyroid" was not used as a search term. "T4" or "thyroxine" could miss some papers of interest.

Finally, the fact that ultimately only studies with significant results were considered does not seem appropriate. Such a strategy is likely to overstate the effects of perchlorate on neurodevelopment. It is important to note that statistical significance is a function of the magnitude of the association and sample size and so estimates from non-significant studies, though imprecise, still have value. Ideally, a summary estimate would be generated from the literature for different outcomes, but studies may not be similar enough to combine estimates.

Claude Emond, Ph.D.

EPA did everything they could to extract from the literature all the data that were required from epidemiological studies.

Dale Hattis, Ph.D.

I have no difficulty and no suggestions for improvement of the document on these issues.

Angela M. Leung, M.D., M.Sc.

The EPA restricted the literature search to studies examining maternal serum FT4 or TT4 levels and offspring neurodevelopment published only after 2000 in order to focus on the most recent science. The Haddow 1999 study was excluded due to the year of publication, as well as the absence of maternal serum FT4 or TT4 levels in the study (the latter is erroneous though). Although it is reasonable to restrict by date of publication, the exclusion of studies that examined only maternal serum TSH concentrations may miss some important data. The Haddow study is a good example of a seminal piece of literature, critical toward a more complete understanding of this topic, that was excluded (or at least placed in Group 3) on this basis.

Overall, the search terms appear to be comprehensive in capturing the desired output.

Of note though, it is unclear why many studies older than the year 2000 were categorized into Group 3, when the search criteria were described in Section 5.1 to be restricted to those later than this cutoff date.

Stephen M. Roberts, Ph.D.

The search strategy used to identify key studies able to inform the quantitative relationship between thyroid hormone levels and neurodevelopmental outcomes is clearly described in the report. The search strategy to identify candidate papers, including search engines and search strings are listed, and the process of selecting the most useful studies through a three step screening process is well described. The rationales for categorization decisions of specific papers is presented in tabular form which offers transparency to the analysis. The criteria for selection of the key studies is reasonable and scientifically appropriate, except for the decision to focus the search on literature after the year 2000. This may have resulted in exclusion of potentially useful studies.

Joanne F. Rovet, Ph.D.

This seems reasonable, although ultimately perhaps a bit too restrictive as some very good studies were eliminated from the final selection. A few critical references are missing (see above). Nevertheless, the quality of analysis was thorough, exhaustive, and very systematic. Unfortunately, most of the studies making the final cut were from Europe, particularly the Netherlands, which I believe has higher iodide sufficiency than the US.

Question 9. <u>Identification of Published Literature and Quantitative Relationship of</u>
<u>Thyroid Hormone Levels to Neurodevelopmental Outcomes</u>. EPA conducted a three-step literature review, which identified 15 studies with information that could inform the quantitative relationship between thyroid hormone levels and neurodevelopmental outcomes.

Question 9B. Please also comment on the summary and characterization of the literature in Chapter 5 of the MCLG Approaches Report and identify any inaccuracies or mischaracterization of the studies.

Hugh A. Barton, Ph.D.

The descriptions of the literature were generally clear and application of the criteria for categorization appeared reasonable. Not having read the original literature, I cannot comment on the accuracy of these summaries. The section includes studies with findings of relationships between thyroid hormone levels and neurodevelopment and studies that do not find such relationships, or do not find relationships for some endpoints. It provides EPA's perspective on the overall database. In the document, EPA indicates that, based upon comments in previous peer reviews, they did not conduct a systematic review. EPA should consider whether a systematic review would strengthen their analysis or if there are steps, such as review of study quality or risk of bias, that could strengthen the analysis without expending the substantial time and resources required for a formal systematic review.

Nancy Carrasco, M.D., M.S.

No comment.

Jonathan Chevrier, Ph.D.

The summary and characterization of the literature in Chapter 5 appeared appropriate to me. However, I note that under column label "Effect Estimates" the note that " $[\beta$ based on untransformed...]" suggests that beta coefficients are shown but odds ratios are sometimes shown (i.e., exponentiated betas). I suggest changing the note to "[Estimates based on untransformed...]". I note that indicating what estimates are shown (i.e. mean change in outcomes, odds ratios or other) would help clarify what is being shown.

Claude Emond, Ph.D.

No comment at this time.

Dale Hattis, Ph.D.

I have no difficulty and no suggestions for improvement of the document on these issues.

Angela M. Leung, M.D., M.Sc.

The reference to T4 in the Oken 2009 study in Table 22 should be clarified as total T4. Other than this, along with the exception the Haddow 1999 study noted above, the summary and characterization of studies as listed in Tables 10-22 appear to be accurate.

Stephen M. Roberts, Ph.D.

Group 2 studies are summarized in tabular form in Chapter 5 and short narrative form in Appendix E; Group 1 studies are described in narrative form in Chapter 5, including tables with key data from these studies. The level of detail provided for both Group 1 and 2 studies is appropriate for the purposes of this report and I did not identify any inaccuracies or mischaracterizations.

Joanne F. Rovet, Ph.D.

This is quite well done and thorough. I was very impressed and appreciated seeing the data digitized for some of the studies. I also liked the evaluation (section 7.1) examining population shifts. I wonder too whether more might be said of the findings from studies that produced the opposite relations that were found and what these findings may be due to or mean.

Question 10. <u>Identification of Published Literature and Quantitative Relationship of</u>
<u>Thyroid Hormone Levels to Neurodevelopmental Outcomes</u>. EPA focused on five studies that evaluated the relationship of maternal fT4 and several neurodevelopmental endpoints (IQ, MDI, PDI and reaction time) based on the measurement of fT4 during early pregnancy at weeks 12, 13 and 16.

Question 10A. Please comment on the assumptions, strengths and limitations of focusing on the five studies and associated neurodevelopmental end points to inform an MCLG, including but not limited to study design, evaluation of neurological endpoints, sample size, iodide nutrition status, potential confounders such as smoking, and study population.

Hugh A. Barton, Ph.D.

One concern is whether there would be a method to allow consideration of the findings of multiple studies, including those with findings that were not statistically significant (either overall or for specific measures, such as IQ or Bayley Scales MDI or PDI). There is mention of a couple of papers that provide meta-analysis, so apparently there are a few studies that are sufficiently similar to be combined. It may be that evaluating the exposure-response using multiple studies is the best approach allowing some estimate of an average and variability.

Nancy Carrasco, M.D., M.S.

Again, although I am not an expert on these kinds of analyses, it seems to me that focusing on these five studies was appropriate and sound, even though it would have been better to have more than five studies, if they existed.

Jonathan Chevrier, Ph.D.

As mentioned above, selecting only studies that reported significant results is likely to overstate the relation between perchlorate and neurodevelopment. Assuming that results are unbiased and that each study sample was selected at random, results from each study represents a point on a distribution of possible results, centered on the true association. Because only one study could be selected for each outcome, it is unclear where published results lie on that distribution.

I think that it is important that EPA take into account the quality of the studies used as part of this exercise. A clear framework for the evaluation of such studies should be developed and applied. Some limitations include:

• Korevaar et al. controlled for instrumental variables (e.g. gestational week at fT4 measurement) as well as variables that are consequences of altered fT4 (e.g. maternal BMI), which may have biased estimates. This study also assumed a log-linear relation between fT4 and the outcome but it is unclear whether the data fit this functional form better than a linear form. Reanalysis of the data performed by EPA should not include the variables noted above,

which may have driven measures of association towards the null, and should investigate the most appropriate functional form to inform decisions about transformation of fT4 values.

- Finken et al. also controlled for BMI in their fully-adjusted model and fit a regression over the entire range of fT4. They do not appear to have investigated functional forms other than a linear relation, although it would be reasonable to believe that fT4 may not affect child neurodevelopment over a certain (normal) range. Authors mention that they standardized fT4 values for the postmenstrual day at which sampling occurred but it is not clear how this was performed.
- Regression coefficients for the studies by Pop et al. were based on very small samples (n=22 and 57) and so it is unclear how reliable these coefficients are. Small studies are more likely to find extreme results and small studies with significant results are more likely to be published. In addition, my understanding is that the scatter plots that were used to derive regression coefficients were not adjusted for confounders. Finally, the predictive potential of Bayley scores at a young age (i.e. 6 months to 2 years) on neurodevelopment at older ages is unclear.

This said, studies by Korevaar et al. and Finken et al. have the advantage of having been conducted on relatively large samples and evaluated neurodevelopment in children aged 5-6 years. However, the fact that all of the studies measured fT4 via immunoassays, which can be biased by the concentration of T4-bound proteins, remains a notable limitation. The fact that no studies were conducted in a U.S. population is also a potential limitation.

Claude Emond, Ph.D.

No comment at this time.

Dale Hattis, Ph.D.

The covered studies are plenty to analyze the likely IQ response to perchlorate.

Angela M. Leung, M.D., M.Sc.

The report focuses on the results of five studies that demonstrate adverse neurocognitive effects of offspring of hypothyroxinemic women (based on serum FT4 concentrations as a continuous measure) during early pregnancy.

• Study design: Study designs were essentially identical, in which measurements of perchlorate, thyroid function, other analytes from banked maternal sera collected during early pregnancy were correlated to at least one measure of neurocognition in their offspring. In the absence of more prospective, adequately-powered studies (i.e., CATS trial), this is the only type of study design that can feasibly assess the longitudinal outcomes of interest many years later.

- Neurological endpoints: This is commented briefly in Section 6.5.2 of the report. The neurocognitive outcomes among the offspring were measured at fairly disparate ages (range: 10 months to 10 years of age). The neurocognitive outcomes were also different and included IQ, reaction time, and psychomotor development. Although these are fairly reasonable differences, given the paucity of published data otherwise, it would be prudent to consult with a psychologist with expertise in childhood test measures and thyroidology to comment on these outcomes. As we know there is continuing development of different structural areas during postnatal neurogenesis (see Bernal J, PMID 17315033), further expertise is needed to correlate whether the adverse outcomes are reasonable with the timecourse of thyroid hormone-dependent neurogenesis.
- Study size: This is commented on briefly in Section 6.5.4 of the report. There was a wide variation in the sample sizes of the five included studies (number of mother-infant pairs): 22, 27, 57, 1765, and 3839. However, even though three of the studies were relatively small, significant associations between maternal hypothyroxinemia and adverse neurocognitive outcomes of interest were still observed. The report did not restrict studies based on small sample size alone.
- **Iodine status**: This is commented briefly in Section 6.5.3 of the report. Among the five studies, urinary iodine concentrations (as a marker of iodine status) were variably assessed. The Korevaar 2016 study (n=3839) assessed urinary iodine in a subset of 672 women and the Vermiglio 2004 study (n=27) measured urinary iodine in the full sample, but the remaining three studies did not at all. If urinary iodine concentrations are abnormally high or low (i.e. both directions outsides of the "adequate" range) in the datasets, adjustment for these values may reasonably alter the strength and/or directionality of the findings. However, as mentioned in question #5 above, there are limitations of using urinary iodine concentrations to interpret iodine status in a given individual. Iodine status is much more reliably measurable on the population level.
- **Potential confounders**: The number and type of potential confounders adjusted for in the five studies varied considerably, as is shown in the footnotes of Table 22.
- Study population: This is commented briefly in Section 6.5.1 of the report. The five studies were conducted mostly in The Netherlands (4 studies), and there was also one small study in Italy (Vermiglio 2004, n=27). Italy has historically been an iodine-deficient country, and although the Vermiglio study measured urinary iodine to categorize the 27 women into 16 who resided in an iodine-deficient region of the country vs 11 who resided in an iodine-sufficient region, the actual urinary iodine concentrations were not used, but rather they were categorical measures used in the analyses examining offspring IQ. The Netherlands has examined only pregnant women for population iodide status (www.ign.org), which in 2002-2006 was considered adequate. This information increases the reliability of the findings in the 4 studies arising from The Netherlands, in which only one measured and adjusted for urinary iodine in a small subset of the study sample.

Stephen M. Roberts, Ph.D.

The final selection of five studies was based principally on the availability of data in a form that could be used to describe the quantitative relationship between maternal fT4 and one or more endpoints related to neurodevelopment. Study designs of these five studies were appropriate to provide the needed information. Smoking as a potential confounder was addressed in some but

not all of the studies, and information on iodine nutritional status was available to varying extents among the studies.

There is some concern that the EPA may not have fully utilized the information available from the epidemiological literature. Specifically,

- 1. Conceivably, raw data from some of the categorical studies (Group 2) might be suitable for developing quantitative relationships between perchlorate and neurodevelopmental endpoints. The EPA should consider approaching study authors about potential availability of data from their study for this purpose.
- 2. The EPA should consider expanding the endpoints considered relevant for assessment of adverse neurodevelopmental outcomes. Examples were provided during the face-to-face panel meeting and appear in comments from other panel members.
- 3. Data from some studies that did not find a statistically significant association between perchlorate exposure and neurodevelopmental endpoints may nonetheless provide useful information, perhaps through combination with data from other studies. Difficulties with combining data in a scientifically sound manner are acknowledged.

Joanne F. Rovet, Ph.D.

I sensed a naiveté in understanding the meaning of the endpoints and their relation to underlying brain function. Despite an excellent appendix describing the relevance of the two BSID versions for Dutch children, I sense some need for caution in interpreting these results. The Bayley scales are a measure of developmental appropriateness and how well the child has achieved the level relevant to peers, whereas Wechsler tests represent how well the child actually performs relative to population norms. Dutch children often score above American. It is interesting to note that the distribution of IQ scores for American children has a different shape and a different midpoint than for Canadian, hence a separate scoring system for the latter. All of these population differences should be understood when making predictions.

As for SDRT, this is an index often used to characterize children with attention disorders and doesn't represent intelligence. However, RT itself may be a gross proxy to intelligence. It is interesting to note too that effects of maternal hypothyroxinemia were mostly on non-verbal perceptual aspects of intelligence and not global IQ itself or verbal IQ. The nonverbal aspects of intelligence are usually subserved by more posterior brain regions that develop earlier than anterior and may receive their thyroid hormone via the choroid plexus.

Question 10. <u>Identification of Published Literature and Quantitative Relationship of</u>
<u>Thyroid Hormone Levels to Neurodevelopmental Outcomes</u>. EPA focused on five studies that evaluated the relationship of maternal fT4 and several neurodevelopmental endpoints (IQ, MDI, PDI and reaction time) based on the measurement of fT4 during early pregnancy at weeks 12, 13 and 16.

Question 10B. Please comment on whether the chosen studies are sufficient in number, quality, and robustness for the purpose of informing the derivation of an MCLG.

Hugh A. Barton, Ph.D.

See comments on 10a.

Nancy Carrasco, M.D., M.S.

I think the studies chosen are sufficient for the purpose of informing the derivation of an MCLG, even though, as I indicated above, a larger number of studies, if available, would have been desirable.

Jonathan Chevrier, Ph.D.

It appears to me that the small number of studies linking fT4 with neurodevelopment and the lack of overlap between studies in terms of outcome are important limitations.

Claude Emond, Ph.D.

The data available are enough in number, but may be very eclectic when compared. The concept linking the reduction of fT4 to neurodevelopment is known; however, the variability between studies, particularly in regard of concentration measured or the origin of the population, may require comparing the methodology used or refining the methodology. I think EPA did great, and more importantly the maximum amount with the information available from epidemiological studies.

Dale Hattis, Ph.D.

The covered studies are plenty to analyze the likely IQ response to perchlorate.

Angela M. Leung, M.D., M.Sc.

The remaining ten studies that also studied these and other neurodevelopmental endpoints, but which did not report significant associations, were not included for the purposes of a perchlorate

MCLG derivation. Excluding these studies lessens the power of the total sample size and thus the ability to detect an association between maternal hypothyroxinemia and any of the offspring outcomes, but provides what may be a somewhat exaggerated estimate of the potential adverse effects of perchlorate exposure. This approach is more conservative, to which there are pros and cons of doing so, toward derivation of a perchlorate MCLG. With this approach, the goal is to minimize exposure to the lowest perchlorate concentration associated with any number of adverse outcomes.

I would favor the more liberal public health approach, which is inclusion of all available studies, whether they are positive or negative. Although the perchlorate MCLG may be higher, this latter approach would be consistent with using all available evidence to improve the scientific rigor of the proposed study question.

Stephen M. Roberts, Ph.D.

While one can always wish for more studies, more subjects, and more endpoints, the chosen studies are sufficient in number, quality, and robustness to inform the derivation of a MCLG. It will be important to more critically evaluate the available studies, however. When strengths and weaknesses of the studies are carefully considered, only a small number may be considered robust enough to use for MCLG derivation. Even one study, if strong, would be sufficient for this purpose, however.

Joanne F. Rovet, Ph.D.

I think this could have been improved by combining the results across the 5 studies using SD or Z-scores and the SD of RT scores (not SDRT) of the groups.

Question 10. <u>Identification of Published Literature and Quantitative Relationship of</u>
<u>Thyroid Hormone Levels to Neurodevelopmental Outcomes</u>. EPA focused on five studies that evaluated the relationship of maternal fT4 and several neurodevelopmental endpoints (IQ, MDI, PDI and reaction time) based on the measurement of fT4 during early pregnancy at weeks 12, 13 and 16.

Question 10C. Please provide advice on reducing any identified limitations.

Hugh A. Barton, Ph.D.

See comments on 10a and 11d.

Nancy Carrasco, M.D., M.S.

No comment.

Jonathan Chevrier, Ph.D.

Given the limitations that I noted above, should EPA decide to go ahead with this approach, I think that models should focus on the most robust studies, i.e. those of Korevaar et al. and Finken et al. but an attempt to integrate strong studies with negative results must be made. The re-analysis of the Korevaar et al. data may be the best avenue given that Finken analyzed data over the entire range and ignored potential nonlinearities. This analysis should not include gestational age at the time of fT4 measurement or BMI as confounders. If measurement error due to variation in gestational age when fT4 was measured is of concern, these values should be corrected to represent values at the same stage (e.g. based on a model relating gestational age and fT4). Also, a model stronger than the linear regression used by EPA would be based on a smoother or other biologically-plausible nonlinear functions which would avoid assuming a linear relation and reduce the influence of outliers or other particularly influential points on the prediction. EPA may want to consider asking Finken et al.'s data to re-analyze data over the lower range of fT4 and/or using smoothers or other biologically-plausible nonlinear functions without controlling for BMI.

Claude Emond, Ph.D.

No comment at this time.

Dale Hattis, Ph.D.

The covered studies are plenty to analyze the likely IQ response to perchlorate.

Angela M. Leung, M.D., M.Sc.

It may be interesting to compare the model outputs if the remaining ten studies in Group 1 (that did not report a significant association between maternal hypothyroxinemia and at least one offspring neurocognitive measure) were included vs. not included in the further analyses.

Stephen M. Roberts, Ph.D.

See response to Charge Question 10a.

Joanne F. Rovet, Ph.D.

I would have liked more discussion on other thyroid disruptors. I would like somewhere that environmental TH disruptors such as bisphenols and triclosans as uncertainties beyond usual goitrogens be mentioned.

Question 11. <u>Identification of Published Literature and Quantitative Relationship of Thyroid Hormone Levels to Neurodevelopmental Outcomes</u>. EPA used regression analyses to predict the magnitude of change in each of the neurodevelopmental endpoints given a change in fT4 as a result of increased perchlorate exposure at different iodide intakes.

Question 11A. Please comment on the assumptions, strengths, and limitations of using the regression analyses to inform the relationship between thyroid hormone levels and neurodevelopmental outcomes. Please also comment on the various functional forms of the regression equations (e.g. linear, log-linear, quadratic) in each of the relationships.

Hugh A. Barton, Ph.D.

Using regression analysis to describe exposure-response appears reasonable. It does not appear appropriate to try to apply some form of PKPD modeling to analyze these results.

Nancy Carrasco, M.D., M.S.

No comment.

Jonathan Chevrier, Ph.D.

As I noted below, the fact that different functional forms were assumed by different studies presents some challenges. First, the distributional form of independent variables should not influence decisions to transform them, as they have little effects on the distribution of residuals in least square (linear) regression. Functional form should either be based on known "exposure"-response relationships or on examination of the data and determination of the form that fits the data best and is biologically plausible.

Although a quadratic form fit the data by Korevaar et al. well over the entire range of fT4 (and the fact that this relation makes biological sense), I support EPA's suggestion to focus on data at the lower range of fT4 to develop their prediction model.

Claude Emond, Ph.D.

The analysis of data, using different regression equations, is not unusual.

Dale Hattis, Ph.D.

As indicated earlier, I believe the regression analyses can and should be improved by substituting Michaelis-Menten transforms for the log(perchlorate) levels in the analyses. See the response to question #3 above.

Angela M. Leung, M.D., M.Sc.

The use of multivariable linear regression would appear to be an appropriate statistical analysis based on the available data, but I defer to the other reviewers with modeling expertise. I have reviewed the summary data presented in Tables 38 and 39, but am unable to comment further on the various functional forms of the regression equations.

Stephen M. Roberts, Ph.D.

The regression analysis is a logical approach to quantifying the relationship between maternal fT4 and various neurodevelopmental deficits. There are a number of limitations and uncertainties associated with this approach that are candidly summarized in Section 6.5.6, including the uncertainties associated with the form of the regression equations. I agree with these limitations and have no additional limitations to add. The report would benefit from clearer explanation of the rationale for the choice of regression form.

Joanne F. Rovet, Ph.D.

This is fine but maybe the meaning of the numbers could be better explained for those less familiar with this approach. Also, the p-values should be given or identified consistently. I think the text could better explain the contents of the table.

Question 11. <u>Identification of Published Literature and Quantitative Relationship of Thyroid Hormone Levels to Neurodevelopmental Outcomes</u>. EPA used regression analyses to predict the magnitude of change in each of the neurodevelopmental endpoints given a change in fT4 as a result of increased perchlorate exposure at different iodide intakes.

Question 11B. Please identify additional data or analyses EPA could use to quantify the relationship between thyroid hormone levels and neurodevelopmental effects, including how this information would be expected to improve the analysis.

Hugh A. Barton, Ph.D.

None identified.

Nancy Carrasco, M.D., M.S.

No comment.

Jonathan Chevrier, Ph.D.

See responses above.

Claude Emond, Ph.D.

No comment at this point.

Dale Hattis, Ph.D.

The use of a Michalis-Menten formulation as indicated in (a) above and in the response to question 3 will provide a more biologically plausible relationship to fit. Because it carries an extra parameter (Km) it will also likely lead to a better fit to the empirical data although a full analysis will need to adjust for this in judging whether the fit is improved enough to justify the added complexity of the model.

Angela M. Leung, M.D., M.Sc.

There are some scant data regarding structural brain size differences in offspring born to hypothyroid women by Dr. Rovet's group, but the classifications of exposure do not appear to have been based on maternal serum FT4 concentrations. There may be additional data regarding morphological brain differences among offspring using maternal FT4 in the future.

Stephen M. Roberts, Ph.D.

I am not aware of any additional data or analyses that could be used to quantify the relationship between thyroid hormone levels and neurodevelopmental effects.

Joanne F. Rovet, Ph.D.

The use of cut-points might be included. The categorical approach needs better explaining.

Question 11. <u>Identification of Published Literature and Quantitative Relationship of Thyroid Hormone Levels to Neurodevelopmental Outcomes</u>. EPA used regression analyses to predict the magnitude of change in each of the neurodevelopmental endpoints given a change in fT4 as a result of increased perchlorate exposure at different iodide intakes.

Question 11C. Please comment on whether there is a magnitude of change in fT4 below which the relationship between fT4 and neurodevelopmental effects should not be used because it is too uncertain.

Hugh A. Barton, Ph.D.

No comment.

Nancy Carrasco, M.D., M.S.

No comment.

Jonathan Chevrier, Ph.D.

No comment.

Claude Emond, Ph.D.

There are 2 things here. First, I agree that the magnitude reported is uncertain; however, it provides a level of change associated with doses. EPA should indicate the level of confidence they have with the value proposed.

Dale Hattis, Ph.D.

I believe there is no such lower limit to the applicability of the analysis.

Angela M. Leung, M.D., M.Sc.

This is commented on briefly in Section 6.5.6 and Table 34 of the report. The reasoning provided, that worse neurodevelopmental outcomes would be biologically plausible and expected with even lower maternal serum FT4 concentrations, is reasonable, and I would not think there would be a specific FT4 cutoff corresponding to a loss of effect.

Stephen M. Roberts, Ph.D.

I am not able to identify a magnitude of change in fT4 that is too small to use for estimating neurodevelopmental effects.

Joanne F. Rovet, Ph.D.

I didn't understand why the 50th percentile values were used.

Question 11. <u>Identification of Published Literature and Quantitative Relationship of Thyroid Hormone Levels to Neurodevelopmental Outcomes</u>. EPA used regression analyses to predict the magnitude of change in each of the neurodevelopmental endpoints given a change in fT4 as a result of increased perchlorate exposure at different iodide intakes.

Question 11D. Please comment on whether other studies that were identified in the literature search (e.g., studies that found categorical relationships between fT4 and neurodevelopmental outcomes, studies that found effects but lacked statistical significance, studies that did not find an effect) could be utilized to quantitatively characterize the relationship between fT4 and neurodevelopmental outcomes or inform uncertainty associated with the analysis presented.

Hugh A. Barton, Ph.D.

It does not seem feasible to develop an exposure response from the categorical findings, but they can be used, as done by EPA, to evaluate qualitatively whether there is consistency between categorical and continuous analyses.

Nancy Carrasco, M.D., M.S.

No comment.

Jonathan Chevrier, Ph.D.

I think that it is important to consider studies that found results that were not statistically significant, especially if sample size is of reasonable size and risk of bias is low. I recommend EPA focus on effect size rather than statistical significance. Studies of good quality that found no effect also have value as they can help estimate the true population values if multiple studies with similar outcomes can be combined. Ideally, multiple studies would be combined in an overall estimate in a meta-analysis together with a confidence interval and this value would be used to predict the impact of perchlorate, but it is possible that too few studies can be combined in this case.

Claude Emond, Ph.D.

I am not aware to any other study, published or not.

Dale Hattis, Ph.D.

My literature search did not identify additional helpful studies.

Angela M. Leung, M.D., M.Sc.

Please also see my comments to Questions #10b and 10c. The literature search produced ten studies (that assessed maternal serum FT4 concentrations as a continuous measure which did not observe an adverse effect on offspring neurocognition), as well as those in Group 2 that assessed serum FT4 as categorical measures. Although their inclusion may not necessarily be recommended in the final model, comparison of the estimated effects on the various neurocognitive outcomes with and without these may indeed inform the degree of uncertainty inherent in the present model. Several of the studies in Group 2 were able to demonstrate significant adverse outcomes (Berbel 2009 as one excellent example), and also their more global nature would help support the generalizability of the present model.

Stephen M. Roberts, Ph.D.

Data from studies that found no effect or effects that lacked statistical significance could in theory contribute to a quantitative characterization of the relationship between fT4 and neurodevelopmental outcomes, but the approach would need to be considered carefully. As the report points out, the absence of an effect (or a significant effect) in some studies may be due to range of fT4 considered. Combining studies that are dissimilar in critical ways would confound rather than improve the derivation of a quantitative maternal fT4-neurodevelopment outcomes relationship. Studies finding categorical relationships can be used to inform uncertainty with the analysis presented, or if raw data from these studies could be obtained, might also provide information on quantitative relationships. See also the response to Charge Question 10a.

Joanne F. Rovet, Ph.D.

Certainly, the CATS study needs to be included. I think the list otherwise was quite complete, but I would have liked more discussion or further highlighting of the Craig study, given it is American and from a very reputable group. I would have liked more discussion on behavioral outcomes, beyond cognitive, such as ADHD and autism and their increased incidence in the population. Author(s) need to include the work of S. Anderson of Denmark on fetal programming of later mental illness and how perchlorate might contribute to this.

Question 12. <u>Alternative Population-Based Approach and Comparison to the Two-</u> Stage Approach Linking Thyroid Hormone Levels to Neurodevelopmental Outcomes.

Please comment on the assumptions, strengths and limitations associated with the population-based approach that is focused on a shift in the proportion of the population that could be considered hypothyroxinemic.

Hugh A. Barton, Ph.D.

This is an appropriate approach for consideration. However, it has the disadvantage of appearing to be focused on potentially transient changes in thyroid hormone levels that one could debate whether the effects are adverse. For the two-stage approach, the end point is clearly adverse; that is, neurodevelopmental deficits in offspring of women who had low thyroid hormone levels. There may be a significant risk communication advantage to having a clearly adverse endpoint as the basis for the MCLG analysis rather than changes in thyroid hormone proportions in the population.

Nancy Carrasco, M.D., M.S.

This topic is outside my area of expertise. I am unable to provide any comments on it.

Jonathan Chevrier, Ph.D.

I believe that this approach has value. Hypothyroxinemia has the potential to impact numerous systems and health outcomes and focusing only on neurodevelopment has the disadvantage of ignoring other health effects of hypothyroxinemia. However, the fact that no clinical definition of hypothyroxinemia exists may complicate communication of the rationale for a MCLG.

Claude Emond, Ph.D.

No comment.

Dale Hattis, Ph.D.

I think the precise definition of "hypothyroxemic" has nothing to do with the real effects of perchlorate on offspring IQ and other relevant parameters of effect. The only relevance is how the medical community reacts with "cases" of "hypothyroxemia" in terms of treatment.

Angela M. Leung, M.D., M.Sc.

This is a reasonable approach to provide a perhaps rough estimate of the magnitude of the impact of perchlorate on a population level, but assumes that there must be an allowable proportion of the population in which maternal hypothyroxinemia associated with potential later adverse outcomes is acceptable. This is in line with some public health perspectives, in which

interventions are implemented to benefit the vast majority (but not all) of those at risk in a given population.

As the report describes in detail (Section 7.2), there are also many assumptions and uncertainties toward deriving this estimate, including but not limited to the definition of maternal hypothyroxinemia during pregnancy; the limitation of the analyses to gestation weeks 12/13/16 since neurogenesis begins as early as gestational week 3; and the choice of what constitutes an allowable hypothyroxinemic proportion of the population.

With both approaches, there are still issues surrounding the definition of adequate iodine status as noted previously (Question #5); the response of TSH to varying degrees of low iodine, low FT4 levels, and perchlorate (separately and additively); and uncertainties regarding duration of perchlorate exposure.

Stephen M. Roberts, Ph.D.

The population-based approach relies upon BBDR modeling to predict the relationship between perchlorate dose and fT4, and thus has all of the strengths and limitations associated with that modeling in common with the two-stage approach. It avoids, however, additional uncertainties associated with extending the model to predict neurodevelopmental outcomes, relying instead on the premise that increasing the percentage of the population of pregnant women that is hypothyroxinemic increases the number of fetuses at risk. A population-based approach also simplifies somewhat estimates of the number of people that might benefit from management of perchlorate in drinking water to specific concentrations. It is supported directly by several studies showing through categorical analysis a relationship between hypothyroxinemia and increased risk of adverse neurodevelopmental effects, and by considering adverse neurodevelopmental outcomes collectively, it encompasses several endpoints of interest and concern. A limitation in this approach is that the explicit endpoint (a decrease in fT4 levels) is not an adverse effect per se, but is instead a precursor effect in a specific population. It is not a scientific limitation, but rather a communication challenge when explaining the approach to some audiences.

Joanne F. Rovet, Ph.D.

I like this approach. I think increasing the population frequency of hypothyroxinemia is a relevant outcome to assess following perchlorate exposure in pregnancy.

On cardiovascular disease, might there be a comparable effect in the offspring, that should be studied.

Question 13. <u>Alternative Population-Based Approach and Comparison to the Two-</u> Stage Approach Linking Thyroid Hormone Levels to Neurodevelopmental Outcomes.

Hypothyroxinemia is the condition of having an abnormally low level of T4 in the blood and TSH is in the normal range, and in diagnosing this condition the threshold for "abnormally low" is often selected to be the 2.5th, 5th or 10th percentile of the population fT4 distribution. Because the BBDR model can be calibrated to any given percentile, but does not predict the distribution of fT4 levels, it was necessary to derive a fT4 distribution to identify a hypothyroxinemic threshold. EPA assumed a lognormal distribution with a Geometric Standard Deviation based on 2 to 3 studies depending on the gestational week. There is uncertainty regarding the true fT4 levels at various percentiles in the distribution around the median output from the BBDR model. For example, some of the analyses show larger unit changes with increasing percentiles of fT4 in most analyses (See tables 24, 30, 31, 32, 33 and Section 6.5.6 of the MCLG Approaches Report). Please comment on the assumptions, strengths and limitations of the derived fT4 distribution for the purposes of this analysis.

Hugh A. Barton, Ph.D.

No comments, as this is outside the reviewer's area of expertise.

Nancy Carrasco, M.D., M.S.

This topic is outside my area of expertise. I am unable to provide any comments on it.

Jonathan Chevrier, Ph.D.

The fact that the model predicts stronger effects at higher levels of fT4 is a major limitation that gives me pause in the use of the model with its current specifications because it makes little biological sense. This may be due to the fact that fT4 was assumed to be log-normally distributed. I think that EPA should evaluate the impact of this choice of a distribution and revert to a normal distribution if models generate results that agree better with our understanding of the biology – i.e., that effects of perchlorate on child neurodevelopment should be stronger among women with low fT4 to begin with. Another possibility for the counterintuitive result may be due to the fact that models of the relation between iodine intake and free T4 were forced to intercept at zero for all percentiles of free T4 (Figure A-54). This forced flatter slopes at lower percentiles. I note that there seems to be little relation between iodine intake and free T4 in the data presented in Figure A-54. EPA should consider whether extrapolation beyond the data and forcing a zero intercept is appropriate. One way or another the discrepancy between the model's results and current knowledge must be reconciled.

Claude Emond, Ph.D.

The strategy used by the EPA is probably the best, considering the availability of the information. It is usually not appropriate to juxtapose different studies, but here it gives us at least a range of information.

Dale Hattis, Ph.D.

I have already commented in some detail on the expected interindividual variability in fT4 levels. See my response to question 7c.

Angela M. Leung, M.D., M.Sc.

The 2.5th, 5th, and 10th percentiles have been the conventional choices in defining a maternal serum FT4 concentration for defining hypothyroxinemia during pregnancy. Section 6.5.6 of the report describes the uncertainties surrounding the selection of a specific cutoff. Negro et al. (PMID 21247845) has also recently reviewed this topic. The current report has selected a 10th percentile FT4 cutoff, and thus presents what may be a relatively higher proportion of women with hypothyroxinemia compared to the lower cutpoints (i.e. the American Thyroid Association defines the condition as the lowest 2.5th or 5th percentile of a given population). I defer to the other reviewers regarding the model code of the derived FT4 distribution.

Stephen M. Roberts, Ph.D.

The observation of larger unit changes with increasing percentiles of fT4 is counterintuitive, which is concerning. The assumption that fT4 is distributed lognormally should be re-evaluated.

Joanne F. Rovet, Ph.D.

My only comment is whether the 10th percentile is too high to be considered "hypothyroxinemia", in the sense of being a clinical condition.

Question 14. <u>Alternative Population-Based Approach and Comparison to the Two-</u> Stage Approach Linking Thyroid Hormone Levels to Neurodevelopmental Outcomes.

Please comment on the strengths and limitations of the two-stage approach versus the alternative population-based approach to inform the derivation of an MCLG.

Hugh A. Barton, Ph.D.

Both approaches are attractive. It is difficult to compare the strengths and limitations of the two methods, as the probabilistic analysis involves many technical elements this reviewer cannot evaluate. While population approaches are desirable, and often model reviewers are uncomfortable when only an average result is presented, it is also frequently true that there is greater uncertainty involved in adequately describing population variability as compared to the population average behavior.

As noted in response to question 12, there may be a significant risk communication advantage to having a clearly adverse endpoint as the basis for the MCLG analysis rather than changes in thyroid hormone proportions in the population.

Nancy Carrasco, M.D., M.S.

This topic is outside my area of expertise. I am unable to provide any comments on it.

Jonathan Chevrier, Ph.D.

The population-based approach certainly has the advantage of relying on fewer assumptions, but it is not clear what threshold should be used to define hypothyroxinemia. The two-stage approach has the advantage of predicting health effects, but the number of studies to derive estimates is small and it is unclear how the negative studies can be integrated in this framework.

A limitation of both methods is that they do not appear to consider the uncertainty of the BBDR model. Estimates are simply taken as is and, in the case of the two-stage model, applied to the confidence intervals of the studies of fT4 and neurodevelopment.

Claude Emond, Ph.D.

No comment.

Dale Hattis, Ph.D.

The MCLG is mostly a policy position. There are, as far as I can see, no real thresholds in the relationships described.

Angela M. Leung, M.D., M.Sc.

Both approaches have their advantages and disadvantages. The two-stage approach is inherently based on more granular individual data, albeit from only a few large datasets drawn primarily from The Netherlands, to estimate discretely decreased maternal serum FT4 levels following perchlorate exposure to result in later adverse offspring neurocognitive outcomes, and thus in theory offers a more stringent estimate of the risks of perchlorate exposure. The alternative population-based approach uses a conventional public health perspective to estimate an allowable proportion of pregnant women to be at potential risk for the adverse offspring effects in order to potentially implement an intervention to decrease risks for the vast majority, but not all, of those who may develop the adverse outcome.

Stephen M. Roberts, Ph.D.

The two-stage approach is consistent with the vision of the 2013 SAB, which is use of a model capable of predicting quantitatively neurobehavioral outcomes in relation to perchlorate exposure. Although additional refinements in the model are possible, especially as new information becomes available, all of the component pieces are in place. The model is informed by, and calibrated to the extent possible using, human data, which is a considerable strength. A limitation of this approach is the limited number of studies available to quantify neurodevelopmental outcomes as a function of perchlorate exposure. The alternative population-based approach has many of the same strengths as the two-stage approach, but stops short of quantifying neurobehavioral outcomes based upon perchlorate effects on thyroid hormone levels. The strengths and weaknesses of this approach are discussed in the response to Question 12.

Joanne F. Rovet, Ph.D.

I am not sure what is meant by the alternative.

Question 15. <u>Alternative Population-Based Approach and Comparison to the Two-Stage Approach Linking Thyroid Hormone Levels to Neurodevelopmental Outcomes.</u>

EPA has developed a two-stage approach linking the revised BBDR model results with quantitative information on neurodevelopmental outcomes from epidemiological studies. Please comment on the utility of the this two-stage approach for predicting potential impact of perchlorate exposure in early pregnancy on neurodevelopmental outcomes in the population at varying levels of iodide intake. Please comment on whether there are better strategies for estimating the potential impact of perchlorate exposure in early pregnancy on neurodevelopmental outcomes that are likely to be more scientifically defensible than the approaches presented (e.g. Appendix C estimates IQ impact directly from perchlorate exposure using Steinmaus et al. and Korevaar et al., or potentially some alternative studies). If an alternative approach would be more appropriate, please outline specifically how the approach might be developed given the current available state-of-the-science and data.

Hugh A. Barton, Ph.D.

Given the limitations of the data, the two approaches considered seem stronger than using the results of a single study to relate perchlorate exposure directly to neurodevelopmental outcomes.

Nancy Carrasco, M.D., M.S.

This topic is outside my area of expertise. I am unable to provide any comments on it.

Jonathan Chevrier, Ph.D.

I commend EPA for engaging in such a complex enterprise. In my opinion, this approach would have greater value if a larger number of studies were available that allowed for the computation of a summary estimate. Although evidence for an impact of maternal fT4 during early pregnancy on child neurodevelopment is convincing, there remains much uncertainty regarding the precise association (in terms of strength and functional form) between these variables. Although apparently not quantified, there is also uncertainty associated with the BBDR model.

The limitations that I mentioned above also apply to the approach presented in Appendix C and so would not help in determining which approach is best. I also note that in this approach log-linear relations were assumed for both models, but I am not sure whether another function fit the data better. In addition, I am not clear why, if epidemiological studies are to be used to derive an MCLG, research investigating relations between prenatal exposure to perchlorate and child neurodevelopment were not used. Attempting to combine results from different studies conducted in different populations certainly adds to the uncertainty and potential for bias.

This said, whether the two-stage or the method presented in Appendix C is based on the confidence that one puts into the BBDR model relative to epidemiological studies, I think that the method from Appendix C could have some value if a large number of studies was meta-analyzed. However, in this particular case only one study was used to evaluate each relation

which is insufficient to predict effects with any reasonable level of certainty. I would thus favor the two-stage approach.

Claude Emond, Ph.D.

No comment.

Dale Hattis, Ph.D.

I think use of the Steinmaus and Korevaar data is the best approach that can be done at present.

Angela M. Leung, M.D., M.Sc.

The use of the two-stage approach, linking the current model to quantitative data from available studies, is reasonable for predicting the population impact of environmental perchlorate exposure. Although the quantitative data are relatively few in number and from primarily a single country, and thus could be improved to add power and generalizability, they do represent probably what is currently known about this evolving topic. Future studies that specifically examine the perchlorate content of banked biospecimens collected during early pregnancy and correlated with offspring neurodevelopmental outcomes would offer more direct and confirmatory evidence of these relationships. Furthermore, animal models may offer additional mechanistic insight of perhaps independent effects of perchlorate on neurogenesis apart from decreasing maternal thyroid hormone levels.

Stephen M. Roberts, Ph.D.

Alternative approaches such as the examples in Appendix C would not be more appropriate than using BBDR modeling. Based upon current understanding of thyroid physiology and the MOA for perchlorate, susceptibility to development of adverse neurodevelopmental outcomes from perchlorate exposure is complex and can be influenced by a variety of factors (e.g., iodide intake, co-exposure to other goitrogens, gestational age). BBDR modeling allows these factors to be addressed explicitly and quantitatively in establishing a safe exposure level for perchlorate. Through modeling, a variety of subpopulations and exposure scenarios of interest can be evaluated. This is more scientifically defensible than basing a MCLG on observations from a single study such as the Steinmaus et al. example in Appendix C. Aside from limitations of this specific study (lack of concurrent timing of measurements of perchlorate exposure and fT4, estimation of perchlorate exposure from a single spot urine sample, measurement of fT4 in the second rather than first trimester, and others), whenever a single study is used there is uncertainty whether the study population adequately represents other populations of interest/concern.

Joanne F. Rovet, Ph.D.

I like this approach and consider it to be state-of-the-art in relation to what is currently available. It represents a significant improvement over the previous modelling approach.

5. SPECIFIC OBSERVATIONS ON REPORT (VOLUME 1)

Hugh A. Barton, Ph.D.

Specific Observations on Report (Volume 1) - Hugh A. Barton, Ph.D.		
Page	Paragraph	Comment or Question
2-2	2	The point of this paragraph is unclear.
2-5	2 of 2.4	Did NRC consider inhibition of iodide uptake nonadverse no matter
		how much inhibition or were they saying that low percentage
		inhibition would be nonadverse? Or, is that not clear?
3-5	Sec 3.2	Merrill et al. 2005 missing from reference list
5-18	Table 12	What does N/A stand for?

Nancy Carrasco, M.D., M.S.

Specific Observations on Report (Volume 1) - Nancy Carrasco, M.D., M.S.				
Page	Paragraph	Comment or Question		
1-2	4	"However, it must be noted that, because the adult euthyroid human thyroid contains several months of T4 stored in the colloid," The claim that the human thyroid stores several months' worth of T4 is a very significant one, yet no reference is provided. Also, a more precise time frame should be given.		
8-1	3	"It must be noted that, because the adult euthyroid human thyroid contains several months of T4 stored in the colloid," Here too, there is no reference.		
3-13	1	"This likely occurs because the half-life of (organified) iodine in the adult thyroid is around six months." Once again, no reference is given.		
1-1	4	"Ingestion exposures are of concern because perchlorate is easily and almost completely absorbed from the gastrointestinal tract (Srinivasan & Viraraghavan, 2009)." In this case, the reference given is a review, and once I located the relevant text in the review, I discovered that there was no reference to a primary research article.		
2-7	3	"There is evidence from cell culture work that perchlorate is actively transported into the thyroid gland and this transport may be enhanced by increasing TSH and reduced in a dose-dependent manner by iodide (Tran et al., 2008). This active transport is potentially due to the upregulation of NIS (Hussein, Abbas, El Wakil, Elsamanoudy, & El Aziz, 2012)."		

Daga	Donoguant	Comment or Question
Page	Paragraph	Comment or Question
		This text is somewhat misleading. The evidence that perchlorate is
		actively transported into the thyroid gland is not limited to results
		from cell culture work. There is in vivo evidence published in
		1959 (Anbar et al.) from the thyroid glands of rabbits and rats, and
		data showing NIS-mediated perchlorate transport into the milk in
		rat dams [Dohán et al., (2009) PNAS]. It is puzzling that the latter
		reference was not included. The authors use a systems biology
		approach to quantitate the inhibition of NIS-mediated I- transport
		at different concentrations of perchlorate.
3-3	1	"In particular, a decrease in fT4 is predicted to increase blood
		TSH, the response to which is an increase in the thyroid NIS
		activity and production rate constants for T4 and T3."
		This statement is not accurate. The direct response to an increase
		in TSH is higher NIS expression: TSH does not directly stimulate
		NIS activity. NIS activity increases only as a result of higher NIS
		expression
3-4	1	"Partitioning of perchlorate into red blood cells and binding to
		plasma protein are included in this model, unlike that of Lumen et
		al. (2013)."
		What is the evidence that perchlorate partitions into red blood
		cells? The plasma membrane is not permeable to perchlorate,
		which is an anion. Thus, NIS is required for perchlorate to be
		translocated across the plasma membrane, and NIS is not
		expressed in erythrocytes. Also, what is the evidence that
		perchlorate binds to plasma proteins?
3-5	2	"The Vmax for NIS-mediated uptake is also increased during
		pregnancy based on independent data."
		It is not clear what the evidence for this claim is, as no reference is
		given. What are the independent data mentioned?
3-5	2	"The perchlorate sub-model is analogous to that of the iodide
		model and describes the assumed mechanism of action for
		perchlorate. That is, once perchlorate is consumed it is distributed
		throughout the body, including to the thyroid plasma, where it can
		bind to NIS, which inhibits the uptake of iodide."
		,
		This statement is inaccurate. Perchlorate does not "distribute to
		the thyroid plasma, where it can bind to NIS, which inhibits the
		uptake of iodide." Rather, perchlorate binds to an anion binding
		site on NIS, after which NIS translocates the perchlorate into the
		cytosol, thus preventing iodide from binding to NIS and being
		translocated into the cell.

Specific	Observations on	Report (Volume 1) - Nancy Carrasco, M.D., M.S.
Page	Paragraph	Comment or Question
2-4	2	"Conditions of low maternal iodine may also cause fetal thyroid function to be impacted once it begins, thereby putting the fetus at risk of developing hypothyroxinemia due to the lack of iodine coming from the mother to create its own thyroid hormone." This statement should be reworded for clarity: Low maternal iodine may also impair thyroid function once it begins, thereby
		putting the fetus at risk of developing hypothyroxinemia because it does not have enough iodine with which to synthesize its own thyroid hormone(s).
3-5	Table 1	"that is adjusted for NIS-mediated uptake in skin and mammary glands"
		What is the evidence that there is NIS-mediated I- uptake in the skin? And regarding the mammary gland, NIS-mediated I-transport has been reported in the lactating mammary gland only, not in the non-lactating mammary gland. This point needs to be made clear.
3-11	Figure 5	How long did the perchlorate exposure last that yielded the data shown in Figure 5?
3-15	4	"The higher PC for perchlorate (80% increase in perchlorate ROB coefficient) reflects the higher ratio of Vmax/Km for NIS-mediated transport into mammary and skin for perchlorate versus iodide. The BBDR model assumes this type of distributional impact of NIS uptake is plausible; however, it has not been evaluated using empirical data."
		Contrary to what this statement suggests, the NIS Vmax and Km for perchlorate have actually been determined experimentally (Dohán et al., PNAS).
3-16	2	"Al-Rasheed et al. (2015) identified several variations in the DNA sequence characterizing the NIS gene as a potential variable influencing the development of differentiated thyroid cancer. While these data are not directly informative within the context of perchlorate, it demonstrates that variability in the NIS gene structure exists and may plausibly represent an important factor rendering individuals more or less sensitive to perchlorate exposure."
		This statement is misleading and inaccurate. The results presented in the paper cited do not indicate that individuals may be more or less sensitive to perchlorate exposure. This is a candidate gene study conducted in a very small cohort. Studies of this type, including this one, were carried out 10 years ago without population stratification or multiple testing correction. More

·····	Specific Observations on Report (Volume 1) - Nancy Carrasco, M.D., M.S.		
Page	Paragraph	Comment or Question	
		importantly, of the 5 SNPs, only one is in an exon, and it is a silent mutation, as the codon still codes for cysteine. Three SNPs are in introns and the last SNP is in the 3' UTR (untranslated region). Therefore, none of the SNPs has any impact or effect on the NIS amino acid sequence or on NIS activity.	
3-17	1	"The association between perchlorate and diminished T4 in the face of elevated TSH (Steinmaus, et al., 2013; Steinmaus, et al., 2007; Blount et al. 2005) suggests that certain segments of the population (low iodide, smokers) respond more weakly than others."	
		The interpretation of the report cited is not correct. The findings presented in this paper do not suggest variability in certain segments of the population. From the way that the molecular mechanism of NIS functions, it follows that when people have low plasma iodide concentrations, there will be more pronounced inhibition by perchlorate. The effect observed in smokers is due to the high concentrations of thiocyanate that smokers have in their plasma. Like perchlorate, thiocyanate is a NIS inhibitor and a NIS substrate.	
3-18	2	"Because it assumes euthyroid status, it does not, for example, address thyroiditis, which is caused by the production of thyroid autoantibodies (e.g., Hashimoto's Disease) and is a relatively common condition that may involve impaired iodide uptake across the NIS and in some individuals, may result in reduced production of T4."	
		This statement is incorrect. Hashimoto's disease is the most common (not a relatively common) cause of hypothyroidism in the US. Therefore, it is not surprising that patients with Hashimoto's disease have lower levels of thyroid hormones.	
3-18	2	"Brent (2010) raises the possibility that perchlorate and similar environmental exposures could increase the risk for Hashimoto's Disease."	
		It is not clear why this statement was included in the report. The Brent paper cited does not even mention Hashimoto's disease.	
3-5		"This inhibition (of NIS by perchlorate) reduces the thyroid's stores of organified iodide, and hence decreases the rate of formation and release of T3 and T4. As fT4 levels decline, the predicted concentration of TSH increases, thereby stimulating iodide uptake and thyroid hormone production, allowing for a partial compensation for the inhibition: the resulting decline in fT4 is less than it would be in the absence of this mechanism."	

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Page	Paragraph	Comment or Question
		This statement is conceptually incorrect, because it mistakenly
		assumes that a rise in TSH will result in increased iodide uptake
		and thyroid hormone production even in the continuous presence
		of perchlorate. What actually happens is that, as long as
		perchlorate is present, even a higher number of NIS molecules at
		the plasma membrane will not transport more iodide; instead, they
		will continue to transport more perchlorate, and there will be no
		compensation whatsoever for the inhibition. Moreover, nowhere
		in the report is it explicitly stated that perchlorate inhibits NIS-
		mediated iodide transport because perchlorate itself is translocated
		by NIS as a substrate. Mechanistically and pathophysiologically,
		there is a very important difference between an inhibitor being a
		blocker and an inhibitor being a substrate. Perchlorate is actively
		transported by NIS; this means that when perchlorate is present, it
		will be accumulated in all the tissues where NIS is expressed,
		including the thyroid, salivary glands, and stomach—and,
		critically, the lactating breast. In other words, if a mother who is
		breastfeeding is exposed to water contaminated with high
		concentrations of perchlorate, she will produce lower levels of
		thyroid hormones, and her newborn will receive perchlorate in the
		maternal milk in addition to receiving less iodide. This twofold
		harm will cause the newborn to synthesize thyroid hormones at
		lower levels at precisely the stage of life at which (s)he is most
		sensitive to inadequate thyroid hormone levels, given that thyroid
		hormones play a crucial role in the development and maturation of
		the central nervous system postnatally.

Jonathan Chevrier, Ph.D.

Specific Ob	Specific Observations on Report (Volume 1) - Jonathan Chevrier, Ph.D.		
Page	Paragraph	Comment or Question	
2-2	2	The last sentence of this paragraph appears to suggest that higher total T4 will result in lower TSH. Is this correct? This would suggest that bound T4 can be detected by thyroid receptors in the pituitary gland and hypothalamus. I suggest that the sentence be re-phrased. The description of this phenomenon in section 2.2 (page 2-3 to 2-4) is more accurate. It is also unclear why this information is repeated in contiguous paragraphs.	
2-5	1	The main effect of thyroid peroxidase (TPO) with regards to hypothyroidism and TPO antibodies is to catalyze 1) the iodination of tyrosine residues and 2) the coupling of iodotyrosine residues in thyroglobulin to form T4 and T3. The conversion of T4 to T3 is primarily handled by iodinases, I would also recommend using a textbook reference rather than a web page	

Page	Paragraph	Report (Volume 1) - <i>Jonathan Chevrier</i> , <i>Ph.D.</i> Comment or Question
Tage	Taragraph	developed for the general public (which is improperly cited in the reference list). Webner and Ignmars' The Thyroid may work for that. Another option is Ruf J and Carayon P (2006) Arch Biochem Biophys; 445(2): 269-277.
3-2	2, last sentence	This sentence appears to be important but was confusing to me. Does this sentence mean that only exposure levels causing fT4 blood concentrations to be reduced at levels that would not be anticipated to trigger an increase in TSH were considered? If so, it appears to me that a better justification for this decision is warranted.
Throughout document		The terms iodine and iodide appear to be used alternatively throughout the document, which can be confusing/distracting. This sometimes happens in the same paragraph, for instance, the last complete sentence of page 3-9 and the sentence beginning on the last line of that same page.
4-2		It is not entirely clear to me how GSDs were back-calculated. The use of an Excel function is not necessary. Values simply need to be logged, an SD of the logged values calculated and then the SD to be exponentiated using the base of the log used for the initial transformation to compute the GSD. Essentially do I understand that 1) data were log-transformed and SDs were calculated, 2) these values were averaged across study populations, and 3) the average values were exponentiated using the base of the log used in step 1? I think this needs to be clarified. This brings another important concern. The standard deviation of combined populations is not equal to the (weighted) average of their standard deviations. The proper formula is: $\sum_{j=1}^{n} (\overline{x_j} - \overline{x})^2 = \sqrt{\frac{\sum_{i=1}^{g} n_i \sigma_i^2 + \sum_{i=1}^{g} n_i (\overline{x_i} - \overline{x})^2}{\sum_{i=1}^{g} n_i}}$ Where g is the number of populations, n_i is the sample size of population i, $x(bar)_i$ is the mean for population i, σ_i is the standard deviation for population i, and $x(bar)$ is the overall average. This would need to be calculated on logged values and then exponentiated. Also, do I understand that data from the Mannisto study were included twice to calculate the 12-13 week GSD values? The fact that these data are not independent needs to be considered in computing these statistics.

Paragraph	In addition, combining these populations requires strong assumptions, i.e. that there is a single population with overall GM and GSD from which each study was sampled. Is this a correct assumption? My understanding is that the distribution of thyroid hormone is population-specific. If that is the case, is it appropriate to combine data from different populations? The fact that no data from a US population is available should be noted as a limitation. Finally, was log-normal distribution expected for fT4? One thing to keep in mind is that immunoassays were used by all studies to measure fT4. Several studies have shown that immunoassays could be biased by the concentration of T4-bound proteins and that physical separation by equilibrium dialysis or ultrafiltration were gold standards to measure fT4. Could this or other factors explain such a skewed distribution of fT4? Also, the use of
	assumptions, i.e. that there is a single population with overall GM and GSD from which each study was sampled. Is this a correct assumption? My understanding is that the distribution of thyroid hormone is population-specific. If that is the case, is it appropriate to combine data from different populations? The fact that no data from a US population is available should be noted as a limitation. Finally, was log-normal distribution expected for fT4? One thing to keep in mind is that immunoassays were used by all studies to measure fT4. Several studies have shown that immunoassays could be biased by the concentration of T4-bound proteins and that physical separation by equilibrium dialysis or ultrafiltration were gold standards to measure fT4. Could this or other factors
	to keep in mind is that immunoassays were used by all studies to measure fT4. Several studies have shown that immunoassays could be biased by the concentration of T4-bound proteins and that physical separation by equilibrium dialysis or ultrafiltration were gold standards to measure fT4. Could this or other factors
	immunoassays to measure fT4 in the studies used should be considered a limitation.
Last	Last sentence: I don't understand how GSDs can be used to represent medians.
1	I did not understand this paragraph. I do not see why a separate GSD needs to be calculated for the low-iodine group and why standard deviations are compared between the 2.5 th and 50 th percentiles vs 50 th and 97.5 th percentiles.
	Certainly, reducing the GSD at lower levels of iodine intake would result in less extreme estimates of fT4 and, presumably, weaker effects of perchlorate than would otherwise be estimated by keeping the GSD constant.
	I also do not understand how the fT4 distributions were computed for different perchlorate exposure levels.
Table 6	Is the exposure level or the internal dose of perchlorate represented here?
1	I think that it is important to mention the consequences of assuming a log-normal distribution over a normal distribution. Presumably, the impact of perchlorate will be estimated to be smaller in the low fT4 concentrations when using a log-normal distribution, which could have important implications for the ultimate objective of this exercise (estimate the impact of perchlorate on lowering fT4 and subsequent effects on child neurodevelopment). I think that more thought needs to be given to the choice of fT4 distribution and its impact on results by conducting sensitivity analysis by running the models assuming a
	Table 6

Specific Observations on Report (Volume 1) - Jonathan Chevrier, Ph.D.		
Page	Paragraph	Comment or Question
		that a log-normal distribution may describe some published results raises concerns about the validity of the results given what is generally reported in terms of distribution.
5-2	Table 9	I was surprised that "thyroid" or "thyroid hormone" were not part of the search terms. I am also surprised that for some outcomes both T4 and thyroxine were used and for others, only thyroxine was used. I can't think of a reasonable rationale for this inconsistency. Also, restricting some search strings to the title may have resulted in missed articles (and using a different strategy for different strings is highly unusual). Although Google Search can list very large numbers of articles, PubMed generally generates a more reasonable number of hits when boolean terms are used (e.g. neurodevelopment AND hypothyroxinemia yielded 45 hits)
5-3	Last	I can see little justification for using only studies that found significant results between fT4 and neurodevelopment. Studies finding no significant results also have values if valid methods were used. Using only significant studies could overestimate the effect of perchlorate on fT4. If EPA believes that this method should be kept, the fact that the model may overestimate perchlorate's toxicity should be acknowledged.
5-4	Last bullet point	Small studies with significant results are generally believed to be more prone to publication bias — this is in fact what is evaluated when using funnel plot to estimate publication bias. Again, by eliminating studies with non-significant results and including small studies with significant results, the model's results may be affected by publication bias and overstate relationships. Also, was any information collected about the quality of the studies including potential for selection, information and/or confounding biases? Studies of poor quality (high risk of bias) should not be considered.
6-3	1	In the following sentence the units for fT4 should be indicated so that the coefficient can be understood.
6-4	Table 24	It is not clear how the confidence intervals were derived for these estimates. Was the uncertainty in deriving changes in fT4 due to perchlorate and changes in the outcome due to changes in fT4 considered? It seems to me that both of these should be reflected in the uncertainty of the prediction. If this cannot be done, only point estimates should be reported (without confidence intervals which, by ignoring uncertainty of the BBDR model will underestimate uncertainty). Also, it makes little sense to me that the effect of perchlorate on
		reaction time would be stronger at the median of fT4 than at the

Specific O	bservations on	Report (Volume 1) - Jonathan Chevrier, Ph.D.
Page	Paragraph	Comment or Question
		2.5 th percentile. Would this be due to the assumed log-normal distribution of fT4?
6-6	Whole page	Here a linear regression was fit on the data representing the lower 50 percent of fT4. Essentially, EPA has decided that values in the higher percentile of fT4 should not influence the shape of the association in the lower 50 percent. EPA could have gone further by fitting a spline on the data, thereby neither forcing a quadratic relation over the range of fT4 but also not forcing a straight line below the 50 th percentile of fT4. This method would also reduce the influence of outliers or other influential points on the beta coefficient (slope).
		Also, a note should indicate whether standard regression assumptions were verified (including the linearity assumption and evaluating the impact of influential points).
		In addition, I note that gestational age at blood sampling for fT4 measurement is not a confounder. This variable is not a causal determinant of IQ and thus, although a determinant of fT4, does not qualify as a confounder (such variables are termed instrumental variables). Also, BMI is a variable that is affected by thyroid hormones and as such not only does it not qualify as a confounder but could be a mediator of the fT4-IQ relation. Controlling for such a variable instrumental variables and mediators is considered to be over-control and can bias estimates of associations (most likely towards the null). Proper control for confounding could affect estimates in Table 26 and (properly) drive them away from the null and generate significant results for the multivariable model.
		Finally, the distribution of fT4 will not determine whether residuals from the linear regression are normally distributed (only the distribution of the outcome will). Therefore, the fact that fT4 was not normally distributed is no reason to log-transform this variable. Log-transforming fT4 assumes that the relation between fT4 and IQ is log-linear (i.e. multiplicative). Is there any reason to believe this? Does this function fit the data better than a linear-linear relation? Answers to these questions are important to ensure that predictions for changes in IQ are accurate and since EPA has the data on hand, they are able to answer them. I also note that the Pop et al. and Vermiglio et al. studies assumed linear-linear
6-11	Table 30	relations with the PDI, which is inconsistent. Here again, I find it difficult to explain that effects of perchlorate

Specific Observations on Report (Volume 1) - Jonathan Chevrier, Ph.D.		
Page	Paragraph	Comment or Question
		than at the 2.5 th percentile. Stronger effects should occur at lower
		fT4 levels and so results suggest problems with the model.

Claude Emond, Ph.D.

No specific observations on the Report provided.

Dale Hattis, Ph.D.

No specific observations on the Report provided.

Angela M. Leung, M.D., M.Sc.

Specific Observations on Report (Volume 1) – Angela M. Leung, M.D., M.Sc.		
Page	Paragraph	Comment or Question
18	Footnote 2	Suggest inserting the word serum before each mention of FT4 and TSH, i.e. "serum FT4 values" and "serum TSH"
20	2	This should read: "TSH acts on the thyroid gland to stimulate iodine uptake to result in decreased thyroid hormone production."
21	2	Suggest that the text regarding suppressed TSH be separated in order to clarify that this does not result from increased serum TBG concentrations. The text would be clearer as follows: "For example, as the first trimester progresses, increases in beta human chorionic gonadotropin (beta-hCG) ⁴ , estrogen, and thyroid binding protein result in a higher serum T4 concentrations, making more fT4 available to the developing fetus (Morreale de Escobar, Obregón, & del Rey, 2007). Serum TSH concentrations are also mildly suppressed due to the action of beta-hCG as a mild thyroid hormone stimulator."
22	1	It is unclear what the two processes are from the ensuing text following this sentence: "In the first trimester of pregnancy, this increased output of thyroid hormones is due to two specific processes ."
23	2	The word "because" is repeated twice. Suggest: "Maternal fT4 is particularly important in the first trimester of pregnancy because the fetal brain is solely dependent upon T4 of maternal origin during this period (Zoeller & Rovet, 2004), as the fetal thyroid gland does not form and become mature until later in development."
23	3	It is unclear what time period this sentence refers to. I think the text is meant to read and should be changed to the following: "Historically, the most commonly observed thyroid conditions

Specific Observations on Report (Volume 1) – Angela M. Leung, M.D., M.Sc.		
Page	Paragraph	Comment or Question
		resulting from hypothyroidism in pregnancy have been goiter (i.e.,
		enlarged thyroid gland) and congenital hypothyroidism."
23	3	Technically, the list refers to hypothyroidism rather than
		hypothyroxinemia, since the latter is relevant only during
		pregnancy. Suggest: "Hypothyroidism may result from iodine
		insufficiency, genetic disorders, autoimmune thyroid disease,
		thyroid surgery, pituitary insufficiency, or environmental factors."
23	4	Hashimoto's thyroiditis does not necessarily cause subclinical
		hypothyroidism, but rather increases the risk of hypothyroidism,
		whether it be subclinical or overt hypothyroidism. (i.e., There is a
		difference between Hashimoto's thyroiditis and hypothyroidism
		resulting from Hashimoto's thyroiditis.) Suggest: "Hashimoto's
		disease increases the risk of hypothyroidism, including both subclinical and overt hypothyroidism. Subclinical hypothyroidism is
		defined by only elevated TSH concentrations, yet serum T3 and T4
		concentrations remain within the population reference range, while
		overt hypothyroidism is defined by elevated serum TSH
		concentrations concurrent with decreased serum T3 and T4
		concentrations."
23	4	The term "clinical hypothyroidism" is confusing and not a
		conventional medical diagnosis. Suggest: "Subclinical
		hypothyroidism has the potential to progress to overt
		hypothyroidism over time , thus requires serum thyroid function
		test monitoring."
24	2	Suggest: "However, since the 2005 NRC report was published,
		several epidemiological studies have shown perchlorate exposure to
		be associated with changes in serum thyroid hormone levels (Blount
		et al., 2006; Steinmaus et al., 2013; Steinmaus et al., 2016) and
		Taylor et al. (2014), as well as an association between high maternal
		perchlorate exposure and risk of low IQ in offspring (Taylor et al.
		2014)."
24	3	I think this should be hypothyroidism instead of hypothyroxinemia,
		as they are not interchangeable. Suggest: "Given the importance of
		a properly functioning thyroid for fetal and child growth (Forhead &
		Fowden, 2014), hypothyroidism may also be associated with
25	Figure 3	abnormal fetal and child growth." Now that hypothyroxinemia pathway has been added, the
23	rigule 3	hypothyroidism box can be confusing. Hypothyroidism in the black
		box is meant to denote a situation of increased serum TSH and
		decreased serum T4/T3 concentrations (i.e. both must be met),
		whereas the blue hypothyroxinemia box denotes a situation of
		isolated serum T4 concentrations (technically this does not include
		T3) in the setting of normal serum TSH concentrations. Thus,
		suggest clarifying with subnotes in each of the hypothyroxinemia
		1 5455651 Clarifying with subhotes in each of the hypothytoxinemia

Specific Observations on Report (Volume 1) - Angela M. Leung, M.D., M.Sc.		
Page	Paragraph	Comment or Question
		and hypothyroidism boxes to indicate the direction of serum T4/T3, T4, and TSH concentrations.
26	1	The word "overt" would clarify the intent of this sentence. Suggest: "Even without the presence of perchlorate as a thyroid disruptor, it is likely that the population is already exposed to a range of thyroid-affecting substances that may result in overt hypothyroidism (elevated TSH, low fT4), subclinical hypothyroidism (elevated TSH, normal fT4), or hypothyroxinemia (normal TSH, low fT4) that will effectively be worsened by exposure to further endocrine disruption caused by perchlorate."
27	2	Consider inserting text to clarify that perchlorate has an approximate 30-fold relative higher potency than iodide to be taken up by thyroidal NIS. PMID 15650353.
28	1	Serum TBG concentrations approximately double (rather than decrease) during the first trimester and remain elevated until the end of gestation, thus this sentence appears to be incorrect. "increases in hCG result in a higher production of T4 and reduced TSH and TBG (Morreale de Escobar et al., 2007)."
32	Figure 4	Suggest either "urine" or "urinary excretion" to maintain consistency throughout.
56	3	Regarding the "Iodine intake data for the study population" bullet, it would also be informative to know the number of subjects the urinary iodine measurements were obtained in. A study sample of >125 individuals is considered reliable when interpreting population urine iodine concentrations measured from a spot urine sample. Small study samples may not be accurate to form conclusions for population iodine status. The size of the study population is addressed in a later bullet, but for different reasons.
95	Table 2	It would be easier to read the table if it was split into the 5 studies for which further analysis was performed for the MCLG derivation and the 10 studies that were not further analyzed.
134	2	Presents an alternative population-based
140	2	In addition, subclinical hypothyroidism (when the serum TSH is elevated but serum T3 and T4 levels remain normal) has been similarly associated with other cardiovascular risk factors, including diastolic hypertension, weight gain, insulin resistance, as well as congestive heart failure and mortality. A brief discussion can be inserted regarding this, which is different from hypothyroidism (inferred as overt hypothyroidism) reviewed in this section. Here are some references regarding adverse cardiovascular outcomes associated with subclinical hypothyroidism: 1. Andersen MN, Olsen AM, Madsen JC, et al. Levothyroxine Substitution in Patients with Subclinical Hypothyroidism and the

Specific Of	bservations o	n Report (Volume 1) – Angela M. Leung, M.D., M.Sc.
Page	Paragraph	Comment or Question
	r	Risk of Myocardial Infarction and Mortality. <i>PLoS One</i> . 2015;10(6):e0129793. 2. Rodondi N, Newman AB, Vittinghoff E, et al. Subclinical hypothyroidism and the risk of heart failure, other cardiovascular events, and death. <i>Arch Intern Med</i> . 2005;165(21):2460-2466. 3. Gencer B, Collet TH, Virgini V, et al. Subclinical thyroid dysfunction and the risk of heart failure events: an individual participant data analysis from 6 prospective cohorts. <i>Circulation</i> . 2012;126(9):1040-1049. 4. Rodondi N, den Elzen WP, Bauer DC, et al. Subclinical hypothyroidism and the risk of coronary heart disease and mortality. <i>JAMA</i> . 2010;304(12):1365-1374. 5. Rhee CM, Curhan GC, Alexander EK, Bhan I, Brunelli SM. Subclinical hypothyroidism and survival: the effects of heart failure and race. <i>J Clin Endocrinol Metab</i> . 2013;98(6):2326-2336. 6. Collet TH, Bauer DC, Cappola AR, et al. Thyroid Antibody Status, Subclinical Hypothyroidism, and the Risk of Coronary Heart Disease: An Individual Participant Data Analysis. <i>The Journal of</i>
		Status, Subclinical Hypothyroidism, and the Risk of Coronary Heart
		2012;00(8):730-737.

Stephen M. Roberts, Ph.D.

No specific observations on the Report provided.

Joanne F. Rovet, Ph.D.

Specific Observations on Report (Volume 1) - Joanne F. Rovet, Ph.D.			
Page	Paragraph	Comment or Question	
X	3	Line 2: "they" referring to wrong referent	
X	3	Line 4: "occurs and that allows for	
X	3	Line 6: "establishes"	
Xi	6	Start with "further" or similar link	
	7	Start with "Second"	
1-1	2	Maybe include idea of airbags	
1-3	2	Change "which" to "that"	
2-1	2	Second last line: change "could" to "can"	
	4	Start with "The"	

Specific	Observations o	n Report (Volume 1) - Joanne F. Rovet, Ph.D.
Page	Paragraph	Comment or Question
		Line 1: perhaps move "largely" to after "act"
2-3	1	Line 2: add "in order" before "to provide"
	1	Line 6: maybe define or introduce hCG if this is the first time mentioned
2-4	3	Line 3: "their respective reference ranges"
2-5	2	Line 8: comma after "published"
2-5	2	Line 10: 2016). Furthermore, Taylor
2-8	3	Section 2.6: add more recent paper
	4	I would expand this paragraph
	6	Add more recent articles
3-3	1	Fourth last line: what's the reference for "it"
3-5	1	Line 3: add a reference after "data"
	2	Third last line "stimulating"
3-9	1	Line starting "In contrast": found this hard to read
3-13	1	Line starting "The similarity": not sure of these assumptions
3-16	2	Middle paragraph "his/her": weren't all of Greer's subjects male?
		Third last line "perchlorate; they demonstrate" (data are plural)
4-2		Not sure what "Distances" mean in Table 4 heading
5-3	5.2.3	Line 3: That is, the studies that were identified found"
5-23	1	Mosaics and Categories need to be capitalized (by convention) as
		these are names of scales. Please do so throughout the report
5-25	1	Lines 2, 3, 5: "nonverbal cognitive delay"
5-25	1	Child ?nonverbal IQ
6-5		Table title: should this read Nonverbal IQ?
6-9	1	Line 5 "Excel, we estimated effects based on" – poor grammar
9-1		Table 39: I don't understand why differences in dose-unit changes are so great – perhaps an explanation somewhere

6. SPECIFIC OBSERVATIONS ON BBDR MODEL (VOLUME 2)

Hugh A. Barton, Ph.D.

Specific Observations on BBDR Model (Volume 2) - Hugh A. Barton, Ph.D.				
Page	Paragraph	Comment or Question		
A-5	1	"GA"?		
A-7	Sec 2.2	"blood plasma" "arterial blood" Is it blood flow or plasma flow? Clarify.		
A-50	2	Change "can" to "scan"		
A-54	5	Change "for iodide for perchlorate" to "for iodide and perchlorate"		
A-71	2	Difficult to follow this paragraph ("The data sets")		
A-84	2	"However, when pREG" is an incomplete sentence		

Nancy Carrasco, M.D., M.S.

No specific observations on BBDR Model provided.

Jonathan Chevrier, Ph.D.

No specific observations on BBDR Model provided.

Claude Emond, Ph.D.

Specific Observations on BBDR Model (Volume 2) - Claude Emond, Ph.D.				
Page	Paragraph	Comment or Question		
A7 (or 13	Middle of	$RNISthy_x = VmaxNIS_thy_x*CthyB_x/[CthyB_x + KmNIS_x*(1)]$		
on pdf)	page	+ CthyB_y/KmNIS_y)]. Some terms are not described below the		
		equation.		
A8 (or14	Paragraph	It is important to note that EPA did corrections from preceding		
on pdf)	in the	version(s) of the model. This is another reason to site the quality of		
	middle	the toxicologist who did the codes for this model.		

Dale Hattis, Ph.D.

No specific observations on BBDR Model provided.

Angela M. Leung, M.D., M.Sc.

No specific observations on BBDR Model provided.

Stephen M. Roberts, Ph.D.

No specific observations on BBDR Model provided.

Joanne F. Rovet, Ph.D.

No specific observations on BBDR Model provided.

7. SPECIFIC OBSERVATIONS ON APPENDICES B-G (VOLUME 3)

Hugh A. Barton, Ph.D.

No specific observations on Appendices B-G provided.

Nancy Carrasco, M.D., M.S.

No specific observations on Appendices B-G provided.

Jonathan Chevrier, Ph.D.

No specific observations on Appendices B-G provided.

Claude Emond, Ph.D.

No specific observations on Appendices B-G provided.

Dale Hattis, Ph.D.

No specific observations on Appendices B-G provided.

Angela M. Leung, M.D., M.Sc.

No specific observations on Appendices B-G provided.

Stephen M. Roberts, Ph.D.

No specific observations on Appendices B-G provided.

Joanne F. Rovet, Ph.D.

Specific Observations on Appendices B-G (Volume 3) - Joanne F. Rovet, Ph.D.		
Page	Paragraph	Comment or Question
E-3	2	Lines 5-7: don't make sense; need a verb
	3	General Cognitive Index
		Line 7: Perceptual needs to be capitalize but scales isn't called - manipulative
		Line 9: Memory; Line 10: Verbal, Numerical; Line 11 Motor – take out skills or scales

Appendix A
List of Peer Reviewers and Biographical Sketches

External Peer Review Meeting for EPA's Revised BBDR Model and Draft MCLG Approaches Report for Perchlorate in Drinking Water



Crystal City Marriott at Reagan National Airport 1999 Jefferson Davis Highway Arlington, VA, 22202-3526

January 29 and 30, 2018

LIST OF PEER REVIEWERS

Hugh A. Barton, Ph.D.

Pfizer, Inc.

Nancy Carrasco, M.D., M.S.

Yale School of Medicine

Jonathan Chevrier, Ph.D.

McGill University Faculty of Medicine

Claude Emond, Ph.D.

University of Montreal

Dale Hattis, Ph.D.

George Perkins Marsh Institute, Clark

University

Angela M. Leung, M.D., M.Sc.

UCLA David Geffen School of

Medicine

Stephen M. Roberts, Ph.D. (chair)

University of Florida

Joanne F. Rovet, Ph.D.

Hospital for Sick Children (Toronto),

Emeritus

BIOGRAPHICAL SKETCHES OF PEER REVIEWERS

Hugh A. Barton, Ph.D.

Pfizer, Inc.

Dr. Barton is an Associate Research Fellow with Pfizer, Inc. in Groton, CT working on mechanistic modeling for pharmacokinetics and pharmacodynamics (PD). Previously he was a toxicologist with the US EPA developing computational models for use in biologically based dose-response analyses, particularly PBPK, for chemical risk assessment. He received his Ph.D. in Applied Biological Sciences from Massachusetts Institute of Technology in 1988. He specializes in the use of PBPK and mechanistic PD modeling to address low dose, interspecies, and inter-route extrapolations that critically impact estimating risks. He has evaluated volatile organic compounds, endocrine disrupting chemicals, and perfluorinated alkyl compounds, most recently focusing on comparisons across life stages. Dr. Barton has been an invited speaker at over 60 presentations, and has published nearly 200 publications, including peer-reviewed journal articles, technical documents, and abstracts. He served on the EPA Science Advisory Board (SAB) Perchlorate Advisory Panel. He has served as a reviewer for several journals including *Journal of Toxicology and Environmental Health, Reproductive Toxicology* and *Toxicology and Applied Pharmacology*. Dr. Barton is currently a member of and has been the President and Vice President of the Society of Toxicology (SOT) Risk Assessment Specialty

Section and the SOT Biological Modeling Specialty Section and a member of the American Society of Pharmacometrics.

Nancy Carrasco, M.D., M.S.

Yale School of Medicine

Dr. Carrasco is a Professor in the Department of Cellular and Molecular Physiology, Yale School of Medicine. She received her M.D. (1980) and M.S. in Biochemistry (1981) from National Autonomous University of Mexico. Her research on the Na⁺/I⁻ symporter (NIS), the key plasma membrane protein that mediates active iodide transport in the thyroid, lactating breast, and other tissues, ranges from biochemical, biophysical, and physiological investigations to translational studies. Dr. Carrasco has served on EPA's Science Advisory Board (SAB) Perchlorate Advisory Panel and in addition, she has been a reviewer (scientific proposal) for a peer review meeting on perchlorate environmental contamination: Toxicological review and Risk Characterization. Dr. Carrasco has been an invited speaker at nearly 100 international meetings, at over 100 seminars, and has authored or co-authored nearly 100 publications/abstracts. In addition, Dr. Carrasco has served on the editorial boards of *Endocrinology, Journal of Bioenergetics and Biomembranes, and Journal of Biological Chemistry* and is a reviewer for several journals including *Clinical Endocrinology, Endocrinology*, and *Thyroid*. She is a member of the American Thyroid Association and the Endocrine Society.

Jonathan Chevrier, Ph.D.

McGill University Faculty of Medicine

Dr. Chevrier is an Assistant Professor in the Department of Epidemiology, Biostatistics and Occupational Health at McGill University, an Associate Member of the McGill School of Environment and Canada Research Chair in Environmental Health Sciences. He received his Ph.D. in Epidemiology from the University of California, Berkeley in 2008. Dr. Chevrier's research program uses traditional and causal inference methods to investigate the potential endocrine-disrupting and neurodevelopmental effects of exposure to persistent and nonpersistent chemicals on child development, thyroid function, and mortality. Dr. Chevrier has been an invited speaker at nearly 30 international, national, and local events, and has authored or co-authored nearly 100 publications including peer-reviewed journal articles (in preparation, under review, published), abstracts/conference presentations, and poster abstract presentations on topics related to human health impact of exposure to common environmental contaminants. In addition, he is an associate editor for American Journal of Epidemiology and serves as an ad hoc reviewer for journals such as American Journal of Epidemiology, Annals of Epidemiology, Critical Reviews in Toxicology, Environment International, Environmental Health Perspectives, Environmental Research, Environmental Science and Technology, Epidemiology, Neurotoxicology, Occupational and Environmental Medicine, Pediatrics. Dr. Chevrier is a member of the Society for Epidemiologic Research and International Society for Environmental Epidemiology.

Claude Emond, Ph.D.

University of Montreal

Dr. Emond is an Adjunct Clinical Professor, Department of Environmental and Occupational Health, Faculty of Medicine, University of Montreal, Montréal, QC, Canada. He received his Ph.D. in Public Health with a concentration in toxicology from University of Montreal in 2001. His main research program is on toxicology and pharmacokinetic and pharmacodynamic modeling of toxic molecules with the objective to understand their mode of action for human health risk assessment. Dr. Emond has presented at 100 lectures, posters, and abstract presentations and has authored or co-authored of over 40 peer-reviewed scientific publications. He served on the EPA Science Advisory Board (SAB) Perchlorate Advisory Panel. In addition, Dr. Emond has been a consultant for US EPA, private company, and academic organizations in PBPK modeling.

Dale Hattis, Ph.D.

George Perkins Marsh Institute, Clark University

Dr. Hattis is a Research Professor with George Perkins Marsh Institute at Clark University. He received his Ph.D. in Genetics from Stanford University in 1974. He has been engaged in the development and application of quantitative methodologies to assess the health impacts of toxic chemicals. His work has focused on approaches to incorporate inter-individual variability data and quantitative mechanistic information into risk assessments for both cancer and non-cancer endpoints. His recent research has explored PBPK modeling of acrylamide dose in rats and humans, mechanism-based dose response modeling of carcinogenic effects from ionizing radiation, age-related differences in sensitivity to carcinogenesis and other effects, and ataxonomy of different non-mutagenic modes of action for carcinogenesis with likely differential implications for age-related sensitivity. Dr. Hattis has authored or co-authored nearly 250 publications and is the primary author of the article entitled "Tests of Three Effect-Addition Hypotheses for the Combined Action of Iodide Dietary Deficiency and Perchlorate on Thyroid Hormone Levels" (2004). In addition, he has evaluated the USEPA/OSWER Preliminary Remediation Goal for perchlorate in groundwater with a focus on exposure to nursing infants. He is a member of the Environmental Health Committee of the EPA Science Advisory Board and was the past Chair of the Dose Response Specialty Group of the Society for Risk Analysis. Has been a member of several National Research Council committees addressing human health risk assessment topics.

Angela M. Leung, M.D., M.Sc.

UCLA David Geffen School of Medicine

Dr. Leung is a Clinical Assistant Professor of Medicine at University of California Los Angeles, David Geffen School of Medicine. Dr. Leung is the Director of the West Los Angeles VA Medical Center thyroid/lipid clinic. Her research focus is in iodine nutrition, thyroid disease, epidemiology, and women's health. She has studied the effects of environmental inhibitors (primarily perchlorate and thiocyanate) on iodine availability and thyroid function in mothers and their infants, the iodine content of U.S. prenatal multivitamins, and factors affecting breastmilk iodine concentrations. She maintains interests in clinical research studies related to iodine status and thyroid function, particularly during pregnancy and lactation. Dr. Leung was the Principal Investigator on a research project examining the relationships between iodine

sufficiency of lactating women and their infants, environmental perchlorate and cigarette smoke exposure, and infant thyroid function. Dr. Leung has been an invited speaker at nearly 50 national and international meetings/workshops, and has authored or co-authored over 100 publications, including peer-reviewed journal articles, reviews and book chapters, editorials, case reports, media interviews, abstracts, and poster abstract presentations on topics related to iodine and the thyroid. Dr. Leung served on the editorial board of the *Journal of Clinical and Translational Endocrinology* and *Thyroid* and is an associate editor for *Clinical Thyroidology* and *BMC Endocrine Disorders*. Dr. Leung serves as an ad hoc reviewer for journals such as *Thyroid Endocrinology* (of *Frontiers in Endocrinology*) and *Clinical Endocrinology*. She is a member of the American Association of Clinical Endocrinology, Endocrine Society, and American Thyroid Association.

Stephen M. Roberts, Ph.D.

University of Florida

Dr. Roberts is the Director of the Center of Environmental and Human Toxicology at the University of Florida. He received his Ph.D. in Pharmacology (1977) from University of Utah, Salt Lake City, UT. His current research interests include mechanisms of drug and chemical toxicity; cell defense mechanisms against toxicity; toxicokinetics, particularly bioavailability of environmental contaminants; risk assessment; nanomaterial toxicity; and novel gene therapy approaches for cancer. Dr. Roberts served as chair on the EPA Science Advisory Board (SAB) Perchlorate Advisory Panel and co-authored the SAB Advice on Approaches to Derive a Maximum Contaminant Level Goal for Perchlorate. He is the Associate Editor and serves on the editorial advisory board of Nanotoxicology and has served on the editorial advisory board of Toxicology and Applied Toxicology, Human and Ecological Risk Assessment, and Dose-Response. He has authored or co-authored over 100 manuscripts, over 100 abstracts or letters and 19 book chapters, and has edited four textbooks: Hazardous Waste Incineration: Evaluating the Human Health and Environmental Risks; Principles of Toxicology: Environmental and Industrial Applications (1st and 3rd editions); and Oxidative Stress in Applied & Basic Research and Clinical Practice. Studies on Experimental Toxicology and Pharmacology. Dr. Roberts is a member of the Society of Toxicology, Society for Risk Analysis, and American Society for Pharmacology and Experimental Therapeutics.

Joanne F. Rovet, Ph.D.

The Hospital for Sick Children (Toronto), Emeritus

Dr. Rovet is a Senior Scientist in Neurosciences & Mental Health Program at The Hospital for Sick Children and a professor of Pediatrics, Psychology, and Institute of Medical Sciences at the University of Toronto. She received her Ph.D. from the University of Toronto in 1983. She has conducted clinical research and her research interests include the role of thyroid hormone in fetal and neonatal brain development, structural and functional neuroimaging studies of children with fetal/neonatal thyroid hormone insufficiencies, thyroid hormone and visual development, and hypothyroxinemia of prematurity and child outcome. A primary focus of Rovet's research program is studying children who were exposed to insufficient levels of thyroid hormone during fetal life and early infant development. Dr. Rovet has consulted to the NIEHS, NIAAA, Environmental Defense League, Health Canada, and the US EPA, having been a member of the EPA Scientific Advisory Board (SAB) Perchlorate Advisory Panel member. Dr. Rover has been an invited speaker at over 50 workshops, and has authored or co-authored over 150 publications,

including peer-reviewed journal articles, technical reports, books, abstracts, and poster abstract presentations. In addition, Dr. Rovet is an editor for *Frontiers in Endocrinology, Thyroid Endocrinology* and *Thyroid Research* and has served on the editorial board of *Thyroid*. She is an elected member of the American Thyroid Association and a member of the Endocrine Society.

Appendix B Meeting Agenda



External Peer Review Meeting for EPA's Revised BBDR Model and Draft MCLG Approaches Report for Perchlorate in Drinking Water

Monday, January 29, 2018 8:30 AM to 5 PM (EST)

Tuesday, January 30, 2018 8:30 AM to 3 PM (EST)

Crystal City Marriott at Reagan National Airport

Potomac Ballroom, Salon D 1999 Jefferson Davis Highway Arlington, VA 22202

Webinar/Teleconference Information

https://artendee.gotowebinar.com/register/4242853031736340995 (415) 655-0060; Code: 902-873-875

AGENDA

Monday, January 29

8:30 a.m.	Meeting Registration & Sign-in
9:00 a.m.	Welcome, Goals of Meeting, and Introductions Karie Riley, Versar, Inc.
9:15 a.m.	EPA's Introduction to the Meeting Eric Burneson, Director, Standards and Risk Management Division, U.S. EPA
9:25 a.m.	Chair's Introduction to the Meeting Stephen Roberts, Chair
9:30 a.m.	Revised BBDR Model / MCLG Approaches Report / Q&A for Panel Paul Schlosser, ORD, U.S. EPA/ Ahmed Hafez, OW, U.S. EPA
10:30 a.m.	Break*
10:45 a.m.	Observer Comment Session Stephen Roberts, Chair
11:30 a.m.	Chair's Review of Charge Stephen Roberts, Chair
11:35 a.m.	Discussion – Round Table General Overview Comments
12:15 p.m.	Lunch*
1:15 p.m.	Discussion - Response to Charge Questions (Initial Question(s))
3:00 p.m.	Break*
3:15 p.m.	Discussion - Response to Charge Questions (continued)
4:45 p.m.	Wrap-up
5:00 p.m.	Adjourn



External Peer Review Meeting for EPA's Revised BBDR Model and Draft MCLG Approaches Report for Perchlorate in Drinking Water

AGENDA (continued)

Tuesday, January 30

8:30 a.m. Recap of Day 1 and Agenda for Day 2

Karie Riley, Versar, Inc.

8:35 a.m. Introduction to Meeting for Day 2

Lisa Christ, Chief,

Targeting and Analysis Branch, U.S. EPA

8:45 a.m. Chair's Review of Charge for Day 2

Stephen Roberts, Chair

8:50 a.m. Discussion – Response to Charge Questions (continued)

10:00 a.m. *Break**

10:15 a.m. Discussion – Response to Charge Questions (continued)

12:00 p.m. *Lunch**

1:00 p.m. Discussion – Response to Charge Questions (continued)

2:50 p.m. Wrap-up/Next Steps

Karie Riley, Versar, Inc.

3:00 p.m. Adjourn

Appendix C List of Registered Observers

External Peer Review Meeting for EPA's Revised BBDR Model and Draft MCLG Approaches Report for Perchlorate in Drinking Water

Crystal City Marriott at Reagan National Airport

January 29 and 30, 2018

LIST OF REGISTERED OBSERVERS

Tina Bahadori (on phone)

U.S. EPA

Betsy Behl (on phone)

U.S. EPA

Erica Bernstein

The Chlorine Institute

Thomas D. Blackman

Lockheed Martin Corporation

Kevin L. Bromberg

Office of Advocacy

Lauren Brown

Abt Associates

Eric Burneson

U.S. EPA

David A. Bussard (in person/on phone)

U.S. EPA

Gail Charnley

HealthRisk Strategies LLC

Lisa Christ

U.S. EPA

Lisa Corey (comments)

Intertox

David Dodge (on phone)

Gradient Corporation

Alia El Burai Feliz (on phone)

U.S. EPA

Jeffrey Fisher (on phone)

U.S. FDA

Lynn Flowers

U.S. EPA

Robinan Gentry (on phone)

Ramboll

Jessica Georges (on phone)

U.S. EPA

Jeff Gibson (on phone)

American Pacific Corporation

Mark Gibson

American Chemistry Council

Jonathan Gledhill

Policy Navigation Group

Scott J. Grare (on phone)

Ingredion Incorporated

Peter Grevatt

U.S. EPA

Ahmed Hafez

U.S. EPA

Evelyn Hamilton (on phone)

U.S. Citizen

Stephanie Hayes Schlea

Association of Metropolitan Water Agencies

Maria Hegstad

Inside Washington Publishers

Erik Helm (on phone)

U.S. EPA

Samuel Hernandez-Quinones

U.S. EPA

Lisa Huff

U.S. EPA

Samantha Jones (on phone)

U.S. EPA

LIST OF REGISTERED OBSERVERS (continued)

Dustin Kapraun (on phone)

U.S. EPA

Kurt Kesteloot (on phone) National Park

Service, Office of Public Health

Elaine Khan (on phone)

Office of Environmental Health Hazard

Assessment

Rajiv Khera

U.S. EPA

Jim Kim (in person/on phone)

Executive Office of the President, OMB

Matthew Klasen

U.S. EPA

April Kluever (on phone)

CFSAN/FDA

Larry Leroy Ladd (comments)

City of Rancho Cordova, California

Emma Lavoie

U.S. EPA

Tom Lewandowski (on phone)

Gradient Corporation

Maria Lopez-Carbo (on phone)

U.S. EPA

Jennifer Mclain

U.S. EPA

Anita K. Meyer (on phone)

USACE Environmental and Munitions CX

Gregory Miller

U.S. EPA

Alexa Moore (on phone)

U.S. EPA

Kevin M. Morley (comments)

American Water Works Association

Mary P. Morningstar

Lockheed Martin Corporation

Viktor Morozov (in person/on phone)

U.S. EPA

Tom Neltner (comments)

Environmental Defense Fund

Darrell Osterhoudt

Association of State Drinking Water

Administrators

Denise Peralta Gailey (on phone)

California Association of Mutual Water

Companies

Richard Pleus (comments)

Intertox

Resha Putzrath

Navy and Marine Corps Public Health

Center Portsmouth, VA

Lawrence Reichle (on phone)

Abt Associates

Kent Richman (on phone)

American Pacific Corporation

Alan Roberson (on phone)

Association of State Drinking Water

Administrators

Jim Rollins

Policy Navigation Group

Jennifer Sass (comments, on phone)

National Resources Defense Council

Paul Schlosser (in person/on phone)

U.S. EPA

Nicole Shao

U.S. EPA

Jamie Strong

U.S. EPA

Clifton Townsend (on phone)

U.S. EPA

LIST OF REGISTERED OBSERVERS (continued)

Patricia Underwood

Office of the Deputy Assistant Secretary of Defense ESOH Directorate

Shradha Upadhayay (on phone)

Metropolitan Water District of Southern CA

Linda M. Wilson (on phone)

NYS Office of the Attorney General

Nicole Yeager

American Water Works Association